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The Impact of Insulin Management on Quality of Life in Type 2 Diabetes

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THE IMPACT OF INSULIN MANAGEMENT ON QUALITY OF LIFE IN TYPE 2 DIABETES

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Knowledge is sweeter than honey.

--James Augustus St. John

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LIST OF ABBRIEVIATIONS

A1C	Hemoglobin A1C
ADA	American Diabetes Association
ADDQoL	Audit of Diabetes-Dependent Quality of Life instrument
ADS	Appraisal of Diabetes Scale
BMI	Body Mass Index
CDC	Centers for Disease Control and Prevention
CIRS	Chronic Illness Resources Survey
CSII	Continuous subcutaneous insulin infusion
DAFNE	Dose Adjustment for Normal Eating
DCCT	Diabetes Control and Complications Trial
DM	Diabetes mellitus
DQOL	Diabetes Quality of Life instrument
DSC	Diabetes Symptom Checklist
DSM	Diabetes-self management
DSQOLS	Diabetes-Specific Quality of Life Scale
HbA1C	Hemoglobin A1C
HRQOL	Health-related quality of life
IDDM	Insulin-dependent diabetes mellitus
MDI	Multiple daily injections (of insulin)
NPH	Neutral Protamine Hagedorn (long-acting insulin)
QLI	Quality of Life Index
QOL	Quality of life
RCT	Randomized controlled trial
SCI-R	Self Care Inventory-Revised
SF-12	Medical Outcomes Study Short Form-12
SF-36	Medical Outcomes Study Short Form-36
SMBG	Self-monitoring of blood glucose
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
W-BQ12	Well-Being Questionnaire 12

ABSTRACT

Complications of type 2 diabetes (T2DM) are severe but can be minimized through excellent glycemic control, optimally achieved by using intensive, or basal-bolus, insulin management. The quality of life (QOL) effects of basal-bolus insulin management are not fully known. This cross-sectional, observational study was based on the Revised Wilson and Cleary Model for Health Related Quality of Life, which measures five QOL domains (biological function, symptoms, functional status, general health perceptions, and overall QOL). The study aims were to describe, compare, and predict QOL in persons with T2DM based on type of insulin management (oral meds only, basal insulin only, or basal-bolus insulin). A convenience sample of adults with T2DM (n=107; 76% women; 84% non-Hispanic whites) completed self-report surveys (Chronic Illness Resources Survey, Diabetes Symptom Checklist-Revised, Well-Being Questionnaire 12, SF-12 Health Survey-version 2, Self-Care Inventory-Revised, Appraisal of Diabetes Scale, Quality of Life Index: Diabetes Version) and a bloodspot HBA1c test via postal mail. The sample reported high QOL (21.8±4.7). Female participants reported lower well-being (23.0 vs 27.5, $p<.01$), greater negative well-being (2.2 vs 1.0, $p<.05$), and lower QOL than study males (21.1 vs 24.0, $p<.01$). Per multiple regression, general well-being ($\beta = .51$, $p<.001$) and appraisal of diabetes ($\beta = -.23$, $p<.05$) predicted QOL [$R^2 = .49$, $F(5, 90) = 17.04$, $p< .001$]. Multiple regression analysis revealed that self-care

moderates the relationship between general well-being and QOL [R^2 = .45, F (3, 102) = 27.73, p<.001]. No significant differences were detected in QOL between insulin management groups. This study may provide greater insight into the QOL in adults with T2DM.

CHAPTER ONE

PROBLEM STATEMENT

Diabetes is a significant cause of death and disability across the world. Diabetes-related complications were documented as the seventh leading cause of death in the US in 2010 (Centers for Disease Control and Prevention [CDC], 2014). The mortality risk for other leading causes of death, such as heart attack and stroke, is nearly doubled by diabetes mellitus (DM; CDC, 2014). Diabetes is the leading cause of new cases of blindness, renal failure, and non-traumatic lower limb amputations in US adults (CDC, 2014). In the US, DM-related complications are costly, resulting in 176 billion dollars of medical costs and over 69 billion dollars of indirect costs related to disability and premature death (CDC, 2014).

Although complications of DM are severe, they can be minimized or avoided through excellent glycemic control (The Diabetes Control and Complications Trial [DCCT] Research Group, 1993; UK Prospective Diabetes Study [UKPDS] Group, 1998). Optimal glycemic control can be achieved through intensive insulin therapy but requires significant patient commitment. Increased hypoglycemia is common with insulin use, especially when given three or more times daily (Frier, 2008; Levy, Christensen, & Johnson, 2008). However, dietary freedom is increased with more frequent insulin

dosing (DAFNE Study Group, 2002) and may lead to increased quality of life (QOL; Manini, Foriani, Moscatiello, Zannoni, Marzocchi & Marchesini, 2007; Ashwell, Witthaus, Bradley, Home & Stephens, 2008). QOL studies in DM managed with basal-bolus, or intensive, insulin dosing have shown mixed findings (Ashwell et al., 2008; Bendik et al., 2009; DAFNE Study Group, 2002; Kalergis, Pacaud, Strychar, Meltzer, Jones & Yale, 2000; Linkeschova, Raoul, Bott, Berger & Spraul, 2002; Schiel & Muller, 1999). As diabetes is a self-managed disease, it is important to understand the impact of insulin management on health-related QOL (HRQOL).

Current treatment recommendations for DM emphasize the use of technology and self-care to optimize glycemic control. Dietary modification and exercise are universally recommended for all patients with DM. Patients with insulin-dependent diabetes (IDDM) include all requiring insulin, regardless of age at diagnosis. Of the 21 million persons with diagnosed DM in the US, approximately 6 million adults require exogenous insulin to survive (CDC, 2014). For these persons, insulin is the foundation of treatment, but cannot be used in isolation to achieve glycemic control. Diabetes self-management (DSM), which combines self-monitoring of blood glucose (SMBG), dietary modification, and exercise, with insulin dosing, is necessary to optimize control of blood sugars (American Diabetes Association, 2014). The “gold standard” of diabetes care is intensive diabetes management, defined as “a mode of treatment for the person with diabetes that has the goal of achieving euglycemia or near-normal glycemia, using all available resources to accomplish this goal” (Wolfsdorf, 2009). Intensive diabetes

management is recommended by the American Diabetes Association (ADA, 2014). Intensive insulin management uses DSM and insulin administered in a basal-bolus format, typically three or more times per day. The doses may be given through multiple daily injections of insulin (MDI) or continuous subcutaneous insulin infusion (CSII) to achieve near-normal levels of blood sugar, as measured by SMBG and glycosylated hemoglobin (A1C). Most patients using basal-bolus insulin management use carbohydrate counting to determine the food-based amount of bolus insulin to be given. Often, intensive diabetes management requires recognition of glycemic patterns over hours or days.

Traditional management of DM also uses medical nutrition therapy, exercise, SMBG, and insulin. However, in this treatment strategy, insulin is given in fixed doses. Some patients with Type 2 DM (T2DM) may be prescribed daily long-acting insulin analogue injections in addition to oral medications. Other patients with IDDM may give insulin once or twice daily, adjusting doses according to a sliding-scale based on SMBG readings. This method of insulin administration is called basal insulin dosing. Patients using basal insulin dosing do not have a prescribed method of adjusting insulin doses based on dietary intake or activity. Thus, for success, this strategy requires eating set amounts of carbohydrates at scheduled times and maintaining a predetermined level of activity.

In reality, despite ADA practice guidelines, intensive diabetes management is not universally used for all patients with IDDM. Although the exact rates of patients using

basal vs. basal-bolus insulin management are not known, basal-only insulin is still used by many patients with T2DM. One strategy used for basal insulin administration of DM is insulin premix, a combination product requiring fixed dietary intake and timing (Henske, Griffith & Fowler, 2009; Hirsch, Bergenstal, Parkin, Wright & Buse, 2005; Niswender, 2009). The use of premix insulin has increased over the last ten years: instead of declining production, leading insulin manufacturers have produced more premix products (e.g., Humalog Mix 75/25, Humalog Mix 50/50, NovoLog Mix 70/30) in response to demand (Lilly USA, 2014; Novo Nordisk A/S, 2014). Why is intensive diabetes management not used universally? Although basal-bolus insulin management can produce optimal glycemic control, it requires substantial patient involvement. Increased hypoglycemia is associated with basal-bolus insulin management (Frier, 2008; Levy, Christensen, & Johnson, 2008). However, more frequent insulin dosing is associated with dietary freedom (DAFNE Study Group, 2002) and may lead to increased quality of life (QOL). From the patient's perspective, QOL may be a more important goal than glycemic control, due to its tangibility. Perhaps because intensive diabetes management is so demanding, glycemic goals are not consistently met by many patients with DM. Per national studies, only 52.5% of patients with DM have achieved glycemic control, as measured by A1C less than seven percent (Casagrande, Fradkin, Saydah, Rust & Cowie, 2013).

Successful intensive diabetes management requires significant patient engagement. Patients' beliefs have been shown to influence treatment adherence in

chronic illness (DiMatteo, Haskard & Williams, 2007). It is likely that perceived QOL benefits can impact adherence to intensive diabetes management. Limited evidence has shown that intensive DM management can increase QOL (Bendik et al., 2009; Hanberger, Ludvigsson, & Nordfeldt, 2009; Menard et al., 2007). However, other QOL studies in IDDM related to basal-bolus insulin management have shown mixed findings, partially due to inadequate measurement of QOL. As DM is a self-managed disease, it is important to understand the impact of intensive insulin management on health-related QOL (HRQOL).

Purpose

The study examined the quality of life in patients with type 2 diabetes according to type of glycemic management. In this study, quality of life is assumed to be a multidimensional construct, including biological, symptomatic, functional, and comprehensive factors. Guided by the revised Wilson and Cleary Model for Health-Related Quality of Life, the study utilized psychosocial instruments and hemoglobin A1C testing to comprehensively assess quality of life in patients with type 2 diabetes according to insulin management strategy.

Theoretical Framework

Wilson and Cleary (1995) proposed a conceptual model of health-related QOL (HRQOL) to define and clarify the multifactorial nature of QOL as related to health. The model was modified by Ferrans, Zerwic, Wilbur, and Larson (2005) to depict the individual and environmental factors that influence HRQOL (Figure 1). In the model,

both the environment and the individual can impact patient outcomes, all of which contribute to HRQOL. Patient outcomes comprise the center of the model and are divided into five types of measures: biological, symptoms, functional status, general health perceptions, and overall QOL (Ferrans et al., 2005). The five types are causally linked to each other, and all are influenced by individual and environmental characteristics. Biological measures are basic physiologic variables such as labs, vital signs, and body mass index. Symptoms are the physical, emotional, and psychological symptoms reported by the patient. Functional status refers to the patient's ability to function physically, psychologically, socially, and in assumed roles. General health perceptions include the patient's subjective evaluation of health, including biological, symptom-related, and functional influences. Finally, overall quality of life is the patient's general satisfaction with life as a whole. The model acknowledges that relationships between model components may be reciprocal but typical directionality is indicated in the arrows (Figure 1). The revised Wilson and Cleary model is useful in directing the assessment of DM-related QOL because it is multidimensional and includes individual and environmental influences.

The concept of quality of life has been depicted in many different ways. The use of a model in quality of life research provides an organizing framework and description of a complex concept. The Revised Wilson and Cleary model has been used to study QOL in a few distinct populations: 1) persons on hemodialysis (Kring, 2008), 2) persons with HIV and liver problems (Henderson, 2007), and 3) patients with T2DM (Chia, 2007).

For patients with T2DM, Chia (2007) found the model to be valid in relating demographic and physiological variables to QOL. The only weakness in using this model in studying QOL in intensive insulin management of DM is that it does not emphasize the complex nature of diabetes self-management. However, self-management can be included in the functional status component of the model. The model is depicted in Figure 1.

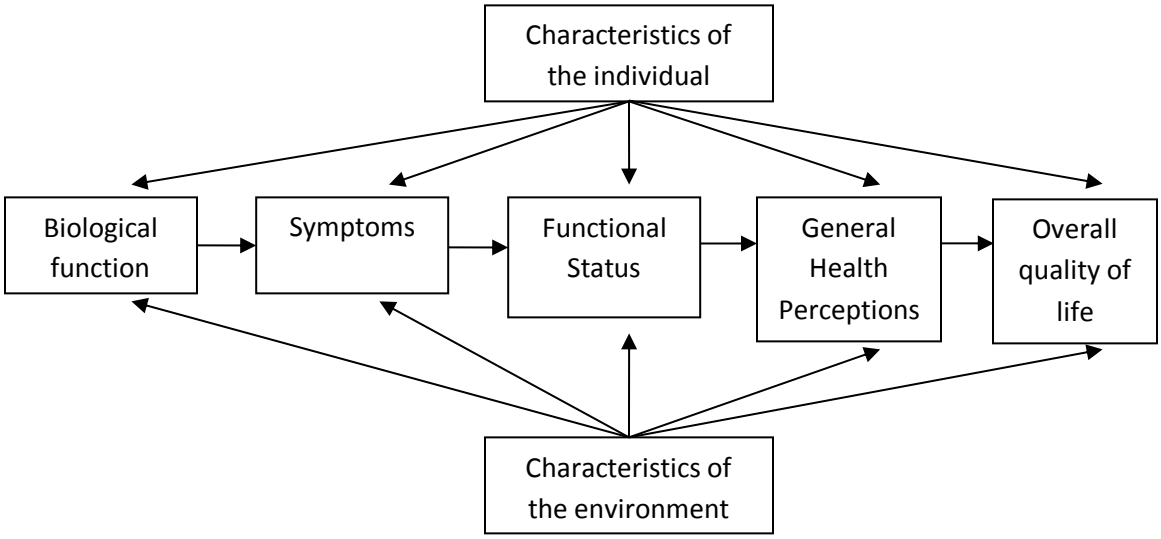


Figure 1. Revised Wilson and Cleary Model of Health-Related Quality of Life

Specific Aims

The aims for this study were (1) to describe the HRQOL of persons with T2DM

according to type of glycemic management [Oral meds only, Basal insulin only (once or twice daily), Basal-bolus insulin (three or more times daily)], (2) to determine if HRQOL of persons with T2DM differs depending on type of glycemic management, and (3) to determine if type of glycemic management is predictive of HRQOL after controlling for covariates.

In summary, QOL in T2DM is a critical construct which has not been adequately studied. The impact of glycemic management strategies in T2DM on QOL has not been determined. The revised Wilson and Cleary Model of Health-Related Quality of Life was used to guide this study of the impact of insulin management on QOL in T2DM. Aims of the study included describing and determining QOL differences based on glycemic management strategy which provided greater insight into QOL in T2DM.

CHAPTER TWO

LITERATURE REVIEW

A literature search was conducted to examine the relationship between intensive diabetes management of DM and QOL which included the years 1996 to 2009 and 32 articles were identified. All articles examined quality of life in intensively managed DM. Databases searched were CINAHL, Medline, PsycINFO, Cochrane, Pub Med, and SSCI. Search limits included English language, human, and research articles. Keywords included: insulin, diabetes, diabetes mellitus, quality of life, flexible, multiple daily, intensive, insulin pump, continuous subcutaneous insulin, and CSI*. Since that time, there have been 12 new studies which are included at the end of this review.

Results

For the 32 studies, the majority of studies in the literature review (n=18) examined QOL in patients already using intensive diabetes management. The remaining studies (n=14) compared various types of intensive diabetes management with traditional treatment, typically fixed-dose insulin. Of the 32 studies in the literature review, five studies examined QOL in CSII; ten studies compared QOL in CSII vs. MDI (Table 1). Ten studies evaluated MDI subjects only (Table 1). Seven studies examined intensive diabetes management by combining CSII and MDI subjects in the same group (n=3) or intensifying the subjects' prior regimens (n=4; Table 1). To summarize the

studies, QOL outcomes will be reported in biologic, symptomatic, psychosocial, and functional dimensions.

Table 1. Intensive Diabetes Management Studies: Sample, Design, and Outcomes

Study	Sample	Design	Outcomes
CSII only			
Aberle, 2009	n=51 German patients w/T1DM Age 36.5±12yr 59% female Educational years 11±3 DM Duration 19±10 years	Cross-sectional descriptive	Glycemic control, QOL, treatment satisfaction, depressive symptoms, coping style, locus of control, self-efficacy
Bruttomesso, 2002	n=138 Italian patients w/ T1DM Age 33±1 years 64% female DM duration 13.1±0.7 years	Cross-sectional: Retrospective descriptive	Glycemic control, QOL (partial data only), severe hypoglycemia, DKA
Gimenez, 2007	n=153 Spain patients w/ T1DM Age 35±11 years 71% female DM duration 18.5±9.5 years	Longitudinal: Prospective, observational	Glycemic control, QOL, severe hypoglycemia, hypoglycemia
Linkeschova, 2002	n=103 German patients w/ T1DM Age 33±11 years 56% female 27% with late complications of DM	Longitudinal: Pre-Post Observational	Glycemic Control, Severe Hypoglycemia; QOL; treatment satisfaction
Ritholz, 2007	n=30 US patients w/ IDDM, CSII users Age 47±9.5 59% female 97% white, 76% married A1C: low (6.8±0.4%)	Qualitative: Focus Groups	Psychosocial factors, self-care, emotional reactions

	mid (7.8±0.3%) high (9.1±0.5%) DM duration 27.3±13.1 years educational years 15.4±1.5		
CSII vs. MDI			
Barnard & Skinner, 2008	n=642 U.K. patients w/ T1DM Age 45±14 69% female DM duration 24±12 years	Cross-sectional matched group survey	QOL, treatment satisfaction, hypoglycemia fear, "problem areas" in DM, glycemic control (proxy measure via SMBG frequency)
DeVries, 2002	All Dutch patients w/T1DM in poor control (A1C≥8.5%) Group A: n=39, age 36±10, 46% female, DM duration 18±10 years, 49% retinopathy; Group B: n=40, age 37±11, 47% female, DM duration 18±9 years, 42.5% retinopathy	RCT: Cross-over	Glycemic control; QOL
Doyle, 2004	All U.S. youth w/T1DM, age range 8-21 years; Group A: n=16, age 12.5±3.2, 63% female, 68% Caucasian, 19% Hispanic, 13% Black, DM duration 7±4 years Group B: n=16, age 13±2.8, 50% female, 81% Caucasian, 13% Hispanic, 6% Black, DM duration 6±4 years	RCT	Glycemic control, QOL (incomplete data)
EQuality1 Study Group, 2008	All Italian patients w/ T1DM, 69% employed Group A: n=481, age 35±11, 57% female;	Cross-sectional case-control	Glycemic control; QOL; treatment satisfaction

	31% retinopathy; Group B: n=860, age 35±12, 46% female, 22% retinopathy		
Herman, 2005	All U.S. older adults w/T2DM (IDDM), age >60 years (mean age 66±5); Group A: n=53, 28% female, 81% Caucasian, 8% Hispanic, 8% Black, DM duration 17±9 yr, 42% retinopathy; Group B: n=54, 64% female, 91% Caucasian, 4% Hispanic, 4% Black, DM duration 15±9 yr; 36% retinopathy	RCT	Glycemic control; QOL; hypoglycemia; treatment satisfaction
Hoogma, 2006	All European patients w/ T1DM Group A: n=129, age 37±11, 53% female; Group B: n=127, age 35±10, 52% female	RCT: 2-way crossover	Glycemic control, Hypoglycemia; QOL; severe adverse events
Hoogma, 2004	All Dutch patients w/T1DM Group A: n=49, age 41±11,73% female, 65% had DM duration >10 years; Group B: n=79, age 43±15 yr, 46% female, 73% had DM duration >10 yrs.	Cross-sectional	Glycemic control; QOL; treatment satisfaction, well-being
Kamoi, 2004	All Japan patients w/ T1DM Group A: n=16, age 48±17, 62.5% female, DM duration 7±6 yr, 13% retinopathy	Longitudinal: Prospective experimental	Glycemic control; QOL; hypoglycemia

	Group B: n=12, age 55±13, 66% female, DM Duration 21±7.9yr, 25% retinopathy		
Scheidegger, 2007	All Swiss patients w/T1DM Group A: n=78, age 43±13, 47% female, DM duration 19±11 yr, 29% retinopathy, 73% professional education, 86% working; Group B: n=81, age 42±11, 48% female, DM duration 17±11 yr, 27% retinopathy, 72% professional education, 89% working	Cross-sectional	Glycemic control; QOL, treatment satisfaction, severe hypoglycemia
	Group L: n=19, age 43±11, 74% female, DM duration 18±11 yr, 47% retinopathy, 68% professional education, 79% working	Longitudinal study	
Tsui, 2001	All Canadian patients w/T1DM Group A: n=13, age 36±12, 38% female, DM duration 17±10 years; Group B: n=14, age 36±10, 29% female, DM duration 15±9yr	RCT	Glycemic control, Hypoglycemia; QOL
MDI only			
Bendik, 2009	n=45 Swiss patients w/ T1DM age 41 (range 18-74), 47% female, DM duration 10 (range 1-49) years	Longitudinal: Pre-Post	Glycemic control; QOL; severe hypoglycemia, locus of control, DM knowledge, SMBG frequency
DAFNE, 2002	N=169 U.K. patients w/	RCT: control	Glycemic control; severe

	T1DM in moderate glycemic control (HA1c 7.5-12%), age 40±9 yr, 56% female, 37% retinopathy	crossover	hypoglycemia; QOL; Psychological well-being; treatment satisfaction, CV risk factors
Gale, 2000	n= 93 U.K. patients w/ T1DM, on MDI Age 35 (range 18-63), 47% female DM duration 13 (range 1-51) years	RCT	Glycemic control; QOL; hypoglycemia
Jansa, 2006	All patients in Spain w/ T1DM, 100% employed or full-time students, race unspecified; Group A: n=19, age 27±11, 47% female, DM duration 12±6 years; Group B: n=16, age 23±5, 31% female, DM duration 10±6 years	RCT	Glycemic control; QOL; hypoglycemia; self-management (SMBG, insulin dose adjustment frequency), DM knowledge
Kalergis, 2000	n=15 Canadians w/ T1DM; Age 38 (range 23-59 yr); 60% female; race unspecified	RCT: crossover	Glycemic control; QOL, self-efficacy, stress, perceived complexity
Langewitz, 1997	n=43 Swiss patients w/T1DM, Age 33±10, 61% female, DM Duration 15±10 years	Longitudinal: Pre-Post	Glycemic control; QOL; severe hypoglycemia, anxiety, depression; self-determination/responsibility; hierarchy MD-patient
Lowe, 2008	n=137 Australians w/IDDM; age 47±15 years; 55% female; 40% T2DM	Longitudinal: Prospective Observational	Glycemic control; self-efficacy; QOL
Manini, 2007	All Italian patients w/ T1DM Group A: n=47, age 46 (range 25-74), 46% female, DM duration 19 (range 4-61) years, 32%	Longitudinal: Pre-post, external group used as controls	Glycemic control; QOL, hypoglycemia

	retinopathy; Group B: n=40, age 44 (range 23-70), 36% female, DM duration 22 (range 7-60) years; 17% retinopathy		
Pfutzner, 1996	n=107 German patients w/ T1DM; age 32±10 years; 50% female DM duration 10±8 years	RCT: control crossover	Glycemic control; QOL; glucose variability, hypoglycemia, adverse events
Zoppini, 2003	All Italian patients w/ T1DM Age 26±6 yr, 43% female, Duration DM 14±7 years	Cross-sectional	Glycemic control; QOL
Intensive Diabetes Management			
Ashwell, 2008	n=48 U.K. patients w/ T1DM; 62.5% female; Group1: Age 42±14 Group2: Age 42±9	RCT: 2-way crossover	QOL; treatment satisfaction
Chantelau, 1997	All German patients w/ IDDM Group A: n=77, Age 32±9, 49% female, 30% retinopathy, 49% white collar job; Group B: n=55, Age 31±8; 49% female; 35% retinopathy; 62% white collar job	Longitudinal: Prospective Cohort (self-selected)	Glycemic control; QOL (satisfaction)
DCCT Research Group, 1996	n=1441 US patients w/ IDDM, age 27±0.3 yrs., 96% Caucasian; Group A: 49% female, 51% retinopathy; Group B: 46% female, 48% retinopathy	RCT: Longitudinal	Glycemic control; DM complications; QOL, psychiatric symptoms, psychosocial event data
Forlani, 2006	All Italian patients w/ T1DM	Longitudinal: Experimental	Glycemic control; QOL; mood/emotional status

	Group A: n=54, age 43 (range 18-65), 62% female; 17% retinopathy Group B: n=36, age 41 (range 26-65), 34% female, 37% retinopathy	Pre-Post (refusers as controls)	
Insabella, 2007	n= 117 U.S. youth w/T1DM Age 14.4±2, 61.5% female, 93% Caucasian, 3.5% Hispanic, 3.5% black, DM duration 5.7±3.7 years	Longitudinal: Prospective	Glycemic control; QOL, depressive symptoms, functional outcomes, DM complications
Schiel & Muller, 1999	All German patients w/ IDDM (T2) Group A: n=40, Age 51±7, 22% female, 23% disabled; Group B: n=77, Age 54±5.9, 41% female, 26% disabled	Cross-sectional descriptive	Glycemic control; QOL; treatment satisfaction; acute/long-term complications
Weinger, 2001	n=55 US patients w/ T1DM using intensive diabetes management, age 34±8, 56% female, DM Duration 9±3 years, NO complications	Longitudinal: Pre-post	Glycemic control; QOL, emotional distress, hypo-glycemia fears, DM hassles, "problem areas" in DM, self-management problems, SMBG frequency

Note. CV = cardiovascular; CSII = continuous subcutaneous insulin infusion; DKA = diabetic ketoacidosis; DM = diabetes mellitus; MDI = multiple daily injections; QOL = quality of life; RCT = randomized controlled trial; SMBG = self-monitoring of blood glucose; T1DM = type one diabetes mellitus; T2DM = type two diabetes mellitus

Intensive Diabetes Management: QOL Dimensions

Biologic

Biologic dimensions of QOL range from demographic factors to glycemic control

and diabetic complications. All have the potential to impact QOL in IDDM. Glycemic control, as measured by A1C, is reported as an outcome in the majority of diabetes studies over the past 30 years (Jeffcoate, 2004). Glycemic control was measured by A1C in 31 of 32 studies. The literature has documented weak relationships between QOL and improved A1C (Barnard, Lloyd & Skinner, 2007). Glycemic variability was examined in select studies of the literature review via glucose profiles, or graphs of seven-point daily SMBG results (DeVries, Snoek, Kostense, Masurel & Heine, 2002), and post-prandial glucose excursions (Pfutzner et al., 1996). The majority of the studies' subjects were in young to middle adulthood, with the exception of older adults in Herman et al. (2005) and two studies of "youth", inclusive of adolescents and young adults (Doyle et al., 2004; Insabella, Grey, Knafl & Tamborlane, 2007). Subjects' age had no significant impact on QOL findings. Diabetes complications (micro- and/or macrovascular) were assessed at baseline by ten studies (Bruttomesso et al., 2002; Chantelau, Schiffers, Schutze & Hansen, 1997; EQuality1 Study Group, 2008, Herman et al., 2005; Insabella et al., 2007; Kamoi, Miyakoshi & Maruyama, 2004; Linkeshova, Raoul, Bot, Berger & Spraul, 2002; Manini et al., 2007; Schiel & Muller, 1999; Zoppini, Carlini & Muggeo, 2003). QOL effects according to DM complication rates were not reported in these 10 studies; however, other studies have examined QOL in DM with complications. The presence of co-morbid diagnoses and DM-related complications significantly decreases QOL in patients with type 2 DM (Goddijn et al., 1999; Lloyd, Sawyer, & Hopkinson, 2001; Solli,

Stavem & Kristiansen, 2010). In the absence of late-stage complications of DM, higher QOL and better glycemic control has been reported in patients with Type 1 diabetes (T1DM; Bott, Mulhauser, Overmann & Berger, 1998). Duration of DM was reported in 21 studies; however, none reported a relationship with QOL. In patients with T2DM treated with oral medications only, increased duration of DM is associated with decreased psychological QOL (β = -0.29, SD = -5.87, P = 0.007; Fal et al., 2010). The majority of the studies do not mention subjects' race or ethnicity. This may be due to the European origin of many studies in the literature review.

Prescribed method of DM control is a biological factor related to QOL. The Diabetes Control and Complications Trial (DCCT, 1993), provided strong evidentiary support for the use of intensive diabetes management as a method for preventing or delaying DM-related complications. QOL did not differ between groups of experimental and control DCCT subjects and remained stable over time (DCCT, 1993). In other studies, intensification of DSM to MDI regimens using analogue insulin was associated with improved QOL over time (Manini et al., 2007; Ashwell, Witthaus, Bradley, Home & Stephens, 2008). Intensive insulin management may provide QOL benefits in comparison to fixed-dose insulin therapy; at the very least, it has not been associated with QOL deterioration. Research has not conclusively proven which type of intensive insulin management, CSII vs. MDI, is superior as related to QOL. Studies comparing CSII and MDI have shown mixed findings. Of the reviewed articles, six studies have shown

significantly improved QOL scores in CSII subjects (Barnard & Skinner, 2008; DeVries et al., 2002; EQuality1 Study Group, 2008; Hoogma et al., 2006; Kamoi et al., 2004; Scheidegger, Allemann, Scheidegger & Diem, 2007). Four studies showed no difference in QOL results between groups of CSII vs. MDI (Doyle et al., 2004; Herman et al., 2005; Hoogma et al., 2004; Tsui, Barnie, Ross, Parkes & Zinman, 2001). It should be noted that all four studies had relatively small samples (n= 32, 107, 49, 27), decreasing the likelihood of detecting significant findings. Method of intensive insulin management is one biological factor that may impact QOL in DM.

QOL in intensively managed DM has been largely studied in T1DM. The majority of reviewed studies examined subjects with T1DM only, with the exception of two studies that enrolled all adults with T2DM (Herman et al., 2005; Schiel & Muller, 1999), and Lowe, Linjawi, Mensch, James, and Attia (2008), who had a mixed sample of T1 and T2DM patients. These studies had mixed findings on the relationship between QOL and intensive diabetes management. In Herman et al. (2005), both groups of adults with T2DM reported increased QOL while in the study; however, subjects using intensive diabetes management did not show a significant difference from controls. In an admittedly underpowered small study (n=117), Schiel and Muller (1999) were unable to detect group differences between subjects using basal-bolus or fixed-dosing of insulin. Lowe et al. (2008) reported a borderline improvement in QOL (p=.05) among subjects using intensive diabetes management; however, approximately 75 percent of subjects

had missing data or did not complete the program. The study of QOL in intensively managed T2DM is incomplete. There is a need to study this phenomenon in persons with T2DM, especially as it is becoming more prevalent. Type 2 diabetes is closely related to sedentary lifestyle and obesity—all are rising to epidemic levels in the United States. In the last 30 years, the incidence of T2DM has doubled in adults (Fox et al., 2006). In 2012, the prevalence of DM was 12.3 percent of U.S. adults, with 90 to 95% T2DM (CDC, 2014). More than one-fourth of adults with DM are insulin-dependent (with or without oral medication; CDC, 2014). Experts recommend the early initiation of insulin therapy in T2DM to protect beta cell mass and function (DeFronzo, 2009; Niswender, 2009). For patients with insulin-dependent T2DM, glycemic control is still the primary goal, best achieved through intensive diabetes management (DeFronzo, 2009). Many patients with insulin-dependent T2DM are not using intensive diabetes management; however, this is expected to change due to the epidemic of T2DM in this country (Niswender, 2009). Although related, T1 and T2DM are not the same illness, differing in age of onset, pathophysiology, progression, duration, and severity. QOL in intensively managed T1 and T2DM cannot be assumed to be the same.

Symptoms

Many DM-related symptoms exist, including those related to hypo- or hyperglycemia. Hypoglycemia is considered to be particularly dangerous and disruptive to patients with DM; indeed, hypoglycemia has been noted to be the single most

limiting factor to obtaining tight glucose control (Cryer, 2008; Heller, 2008). Intensive insulin management increases the frequency of hypoglycemia (DCCT, 1993): one estimate reported that on average, a patient with intensively managed T1DM experiences up to 10 episodes of symptomatic hypoglycemia per week and at least one episode of severe hypoglycemia per year (Briscoe & Davis, 2006). However, hypoglycemia is somewhat abated by the use of rapid-acting analogues and CSII (Cryer 2008; Heller, 2008; Pfutzner et al., 1996; Gale, 2000). CSII may be associated with less frequent or severe hypoglycemia than MDI (Fatourechi et al., 2009). QOL is decreased by hypoglycemia that is frequent (Tierney et al., 2008) or severe (Davis et al., 2005). Of the studies reviewed, over half assessed hypoglycemia by patient report, medical record review, or glucose meter downloading (n=19; Table 2). Most useful is the assessment of severe hypoglycemia, defined as hypoglycemia requiring assistance of another person. Severe hypoglycemia is disruptive, alarming, and dangerous, producing significantly negative QOL effects. Thirteen of the reviewed studies examined rates of severe hypoglycemia (Table 2). Significant decreases in severe hypoglycemic episodes were strongly associated with QOL improvement in five studies (Table 2). Changes in mild or overall hypoglycemia were shown to be associated with QOL improvement in a few studies (n=4; Table 2). For patients treated with insulin, regardless of DM type, hypoglycemia is a frequent reality, with overall (mild to severe) prevalence of up to 93 percent (Zammitt & Frier, 2005). Hypoglycemia is less frequent in insulin-dependent

T2DM, with a rate of 16 events of overall hypoglycemia per patient-year, compared to 43 events per patient-year in T1DM (Briscoe & Davis, 2006). Due to physiologic differences, patients with T2DM experience hypoglycemia with less severity and more warning symptoms (Zammitt & Frier, 2005). Only one study examined hypoglycemia and QOL in T2DM; no significant relationships were detected (Herman et al., 2005).

Table 2. Hypoglycemia and Quality of Life: Longitudinal Studies and Randomized Controlled Trials

Study	Hypoglycemic Frequency		QOL effects		Other
	Baseline	Follow-up	Baseline	Follow-up	
Severe Hypoglycemia					
Bendik, 2009	Events/6 months		DQOL: ↓score= ↑QOL		
	.33	.03 *	91.8±22.5	85.6±20.0***	
Bruttomesso, 2002	Events/year		DQOL		
	.31±0.07	.09±0.02 **	--	73.0±1.8	
DAFNE, 2002	% patients with ≥1 event/6 months		ADDQOL: AWI		QOL between groups at 6 months**
Experimental	22	18	-2.0±1.6	-1.6±1.6	
Controls	11	15	1.9±1.3	-1.9±1.4	
DCCT, 1996	≥1 event in last year	Events/100 patient-years	DQOL:		No change in QOL
Intensive	5% of subjects	62***	78±8	78±9	
Controls	4% of subjects	19	78±9	78±9	
Doyle, 2004	Events/16 weeks				*B*aseline HYPO not reported
CSII	--	2	No change in QOL; data not reported		
MDI	--	5			
Gimenez, 2007	Events/patient-year		DQOL: impact		All subscales of DQOL improved, no total scores given
Severe HYPO	0.31±0.46	0.07±0.25***			
Overall HYPO (>5/week)	44% of subjects	5% of subjects***	44.8±9.5	39.5±7.4***	
Herman,	Events/patient-year		DQOL-CTQ: Impact scores		Severe HYPO

2005 CSII MDI				increased +2 points from baseline in both groups**, no between group differences	shown/no differences in mild HYPO; T2DM's
	--	.08			
	--	.23			
Hoogma, 2006	Events/patient-year		DQOL total:		↓severe HYPO and ↑QOL in CSII at follow-up***
CSII	--	0.2	--	75	
MDI	--	0.5	--	71	
Insabella, 2007	No events in last 6 months	16.7 events/ 100 patient-years	DQOL-Y: Impact 47±3	43±6 (n.s.)	*Severe* HYPO **increased**, no sig reported
Langewitz, 1997	% of patients w/ event last year 18.6	7*	DQOL: satisfaction 33.3±8	25.8±7.7***	
Linkeschova, 2002	Cases/patient-year 0.70	0.06***	All subscales of DSQOLS improved (p=.025-.000); no total scores given		
Scheidegger, 2007	50 events in 228 subject-months	1 event in 104 subject-months	DSQOLS: 248±45	277±34*	No sig. reported for HYPO data
Tsui, 2001	No between-group or over time differences		No between-group or over time differences		*Severe* and *mild* HYPO
Mild Hypoglycemia					
DeVries,2002	Events/week		SF-36: General, Mental		No differences in severe HYPO (not shown)
CSII	2.13±2.05	.98±2.02*	--	+5.9*, +5.2	
MDI	1.97±1.53	-.02±1.18	--	-1.2, -0.6	
Jansa, 2006	% of patients with ≥3 events/ week		DQOL: Impact		No between-groups differences at any time; Only DQOL impact scale sig. (others n.s.)
Telecare	75	6***	44±6	41±7 (n.s.)	
Controls	79	15***	43±7	38±6*	
Nocturnal Hypoglycemia					
Gale, 2000	Events/month		No change in QOL; no scores reported		Overall HYPO rates not
Lispro	--	0.7 ±1.6***			

Controls	--	1.8±3.1			shown (n.s.)
Overall Hypoglycemia					
Kalergis, 2000	20 events/100 patient-years		DQOL (total scaled score): 2.0±0.1		No change from baseline or between groups
Kamoi, 2004	Events/3 months		ITR-QOL:		Odd HYPO stats (n.s.); QOL difference between groups**
MDI	10.8±23.9	6.3±12.6	80.2±20.9	86.3±21.8	
CSII	0.9±1.6	0.5±1.4	99.4±13.3	101.8±11.6	
Pfutzner, 1996	Events/month				No baseline HYPO rates reported; less HYPO during lispro (than w/ regular human insulin)**
Lispro	--	8.57±0.7 **	QOL: satisfaction improved in lispro group; no differences in other domains		
Controls	--	9.61±0.72			

Note. -- No data provided by study authors.

ADDQOL-AWI = Audit of Diabetes-Dependent Quality of Life—Adjusted Weighted Index; CSII = continuous subcutaneous insulin infusion; DQOL = Diabetes Quality of Life instrument; DQOL-CTQ = Diabetes Quality of Life—Clinical Trial Questionnaire; DQOL-Y = Diabetes Quality of Life—Youth; DSQOLS = Diabetes-Specific Quality of Life Scale; HYPO = hypoglycemia; ITR-QOL = Insulin therapy-related—Quality-of-Life instrument; MDI = multiple daily injections; QOL = quality of life; SF-36 = Medical Outcomes Study Short Form-36; T2DM = type two diabetes mellitus

*p<.05, **p<.01, ***p<.001

Hyperglycemia can also impact QOL. In patients with T2DM, symptoms of high blood sugar have been associated with decreased QOL (Goddijn et al., 1999). Symptoms of hyperglycemia were assessed in the DCCT (1996) and by Jansa et al. (2006); no relationship between these symptoms and QOL was detected. Diabetic ketoacidosis, usually requiring hospitalization, has substantial potential to impact QOL and was

assessed by six studies (Bruttomesso et al., 2002; Doyle et al., 2004; Gimenez et al., 2007; Linkeschova, Raoul, Bott, Berger & Spraul, 2002; Schiel & Muller, 1999; Tsui et al., 2001). Symptoms related to glycemic extremes have strong effects on QOL.

Patients with DM have other symptoms which can affect QOL. More recently, symptoms of emotional distress (e.g., anxiety, depression, DM-related distress) have also been shown to have a significant impact of QOL as well. Psychological distress is reportedly experienced by one-third of young adults with T1DM (Hislop, Fegan, Schlaeppi, Duck & Yeap, 2008). In a study of 51 adults on CSII, depressive symptoms significantly correlated with lower QOL ($r=-0.542$, $p<0.01$; Aberle et al., 2009). As compared to peers without DM, patients with T2DM have increased depression, which results in decreased QOL, especially in those patients prescribed insulin (Aikens, Perkins, Piette & Lipton, 2008). Less depressive symptoms and DM-related distress are related to improved QOL and glycemic control (Langewitz, Wossmer, Iseli & Berger, 1997). Other studies have examined psychological symptoms as related to QOL, including anxiety and DM-related distress (Table 3). Presence of symptoms due to complications of DM can decrease QOL (Garratt, Schmidt, Mackintosh & Fitzpatrick, 2000). Chronic pain and visual impairment are associated with decreased QOL in patients with T2DM (Boutoille, Feraille, Maulaz & Krempf, 2008; Smith et al., 2008). In the literature review, no significant relationship between QOL and DM-complications was reported; however, this relationship was not often examined. One unexpected finding was the decreased

energy levels in patients with T2DM on basal-bolus insulin management, compared to controls using fixed insulin dosing (Schiel & Muller, 1999). Patients with DM have reported increased suicidal thoughts and lower QOL than similar peers without DM (Pompili et al., 2009). Clearly, many symptoms can affect QOL in patients with IDDM.

Table 3. Psychosocial Outcomes and Quality of Life

Outcome	Study Design		
	Cross-Sectional	Longitudinal	RCT
Depressive Symptoms or Depression	Aberle, 2009	Insabella, 2007 Langewitz, 1997	
Anxiety		Langewitz, 1997	
Coping	Aberle 2009		
Self-efficacy	Aberle, 2009	Linkeschova, 2002 Lowe, 2008	
Locus of Control	Aberle, 2009		
Self-control		Bendik, 2009	
Self-determination/self-responsibility		Langewitz, 1997	
DM-related emotional distress	Barnard & Skinner,2008 Bruttomesso, 2002 Hoogma, 2004 Zoppini, 2003	Bendik, 2009 Chantelau, 1997 Forlani, 2006 Gimenez, 2007 Insabella, 2007 Langewitz, 1997 Weinger, 2001	DCCT, 1996 Doyle, 2004 Herman, 2005 Hoogma, 2006 Jansa, 2006 Kalergis, 2000 Tsui, 2001
Social worries	Bruttomesso, 2002 Hoogma, 2004 Scheidegger, 2007 Zoppini, 2003	Bendik, 2009 Chantelau, 1997 Gimenez, 2007 Insabella, 2007 Langewitz, 1997 Linkeschova, 2002 Scheidegger, 2007 Weinger, 2001	DCCT, 1996 Doyle, 2004 Herman, 2005 Hoogma, 2006 Jansa, 2006 Kalergis, 2000 Tsui, 2001

Well-being	Forlani, 2006	DAFNE, 2002

Note. DCCT = Diabetes Control and Complications Trial; DM = diabetes mellitus; RCT = Randomized Controlled Trial

Psychosocial

For patients with IDDM, psychosocial dimensions can have considerable impact on QOL. Intensive diabetes management requires self-efficacy and self-motivation. Table 3 reports psychosocial constructs examined by studies in the literature review. Aberle et al. (2009) found that among CSII users, higher self-efficacy was correlated with better QOL and less depressive symptoms ($r=0.601$ and -0.453 respectively, $p<0.01$). In the same study, locus of control was found to be the most significant predictor of A1C ($R2=0.479$, $p<0.01$), with a significant correlation between high external locus of control and increased A1C ($r=0.56$, $p<.01$). In a focus group study, an external locus of control was commonly found in CSII subjects in poor glycemic control (A1C>8.0%; Ritholz et al., 2007). In the same study, focus groups with well-controlled T1DM (A1C<7.0%) reported using an active approach to DSM and feeling more "normal" since beginning CSII (Ritholz et al., 2007). Weinger and Jacobson (2001) conducted a prospective study of 55 adults with T1DM. The subjects attended an intensive diabetes management clinic and educational program over four to five months. The study revealed that patients with improvements in DM-related emotional distress also improved their glycemic control ($r=0.38$, $p<0.02$) and satisfaction-related QOL ($p<0.001$). Intensive diabetes management can impact psychosocial outcomes: initial functional insulin therapy

testing showed a reduction in depression and anxiety after training (t=4.37 and 5.52, p<0.001; Langewitz et al., 1997). These preliminary studies clearly indicate a relationship between psychosocial outcomes and QOL in intensively managed DM, but further inquiry is required.

Functional Status

Patients' ability to function physically, emotionally, and socially is a primary determinant of QOL. Cognitive function is an important component of role performance. Increased AIC over time has been linked to cognitive dysfunction or decline in elderly and young adult patients with DM (Munshi et al., 2006; Musen et al., 2008). In a large, multi-site, longitudinal randomized controlled trial of patients with IDDM, neither intensive insulin management nor severe hypoglycemia had an impact on cognitive performance in young adults (Musen et al., 2008). Physical abilities also affect role performance. Decreased mobility and activity tolerance due to DM-related complications has been linked to lower QOL scores (Boutoille et al., 2008). In a study of 53 young adult T1DM patients, self-reported regular exercise was significantly associated with higher QOL (p<0.05, Forlani, Zannoni, Tarrini, Melchionda & Marchesini, 2006). Frequent hypoglycemia is linked to decreased work productivity in patients with T1 and T2DM (Davis et al., 2005). Of the literature reviewed, only four examined employment (Forlani et al., 2006; Scheidegger et al., 2007) or functional outcomes

(Insabella et al., 2007; Jansa, et al., 2006) as related to QOL; no significant findings were reported.

One critical functional dimension for patients with DM is self-care, or the performance of DSM behaviors. Successful performance of DSM has been linked to higher QOL (Ayalon, Gross, Tabenkin, Porath, Heymann & Porter, 2008). Of the studies in the literature review, none reported deterioration in QOL, despite the implementation or continuation of complex and time-consuming DSM behaviors. Some studies (n=6), reported increased QOL after changing from fixed-dose to basal-bolus insulin management (Bendik et al. 2009; Chantelau et al., 1997; DAFNE Study Group, 2002; Langewitz et al., 1997; Linkeshova et al., 2002; Lowe et al., 2008). Table 4 reports self-care practices measured by the studies of the literature review. SMBG frequency was documented in one-fourth of the studies in the literature review (Table 4). In T1DM, increased frequency of SMBG has been linked to improved glycemic control and QOL (Schiel & Muller, 1999). Self-adjustment of insulin doses according to activity, food, and SMBG results is an important DSM behavior in intensive insulin management. While only measured by a few studies in the literature review, higher frequency of insulin dose self-adjustment was associated with improved glycemic control (Jansa et al., 2006; Schiel & Muller, 1999) and QOL improvements (EQuality1 Study Group, 2008; Jansa et al., 2006). For patients with T2DM using intensive insulin management, self-

adjustment of insulin doses was not associated with improved QOL (Schiel & Muller, 1999).

Table 4. Self-Care Measures and Quality of Life

Self-care activity	Study Design		
	Cross-sectional	Longitudinal	RCT
Diet	EQuality1 Study Group, 2008	Lowe, 2008	
Exercise	Zoppini, 2003	Lowe, 2008	
SMBG frequency	Barnard & Skinner,2008 Hoogma, 2004 Scheidegger, 2007 Schiel & Muller, 1999	Bendik, 2009 Scheidegger, 2007 Weinger, 2001	Doyle, 2004 Jansa, 2006
Insulin dose adjustment	EQuality1 Study Group, 2008 Schiel & Muller, 1999		Jansa, 2006
"Self-management"		Weinger, 2001	

Note. RCT = Randomized controlled trial; SMBG = self-monitoring of blood glucose

Kalergis et al. (2000) examined the relationship between self-management and QOL in a very small study of adults with T1DM (n=15). Pre-study insulin regimens were MDI with minimal to no self-adjustments of insulin doses. Three treatment strategies were used: simplified, qualitative, and quantitative. In the simplified strategy, subjects had a set meal plan and were permitted insulin self-adjustments based on SMBG results only. In the qualitative strategy, subjects were permitted to self-adjust insulin

qualitatively based on SMBG results, food intake (according to food exchange lists), exercise, and stress. In the quantitative strategy, subjects used carbohydrate counting, insulin-to-carbohydrate ratios, and correction factors to self-adjust insulin doses for SMBG results, food intake, exercise, and stress. All subjects (n=5 per group) followed each strategy for 3.5 months before rotating. The groups did not significantly differ in terms of metabolic control (A1C), frequency of severe hypoglycemia, QOL, or self-efficacy. As expected, the most frequent dose adjustments were made in the quantitative regimen ($p<0.01$). The same strategy, quantitative, was also perceived as the most complex ($p<0.001$). Surprisingly, at the conclusion of the study, the majority of patients (n=12) chose to continue with the qualitative regimen, whereas only three subjects continued with the quantitative strategy. The authors concluded that patients with T1DM would prefer an intensive insulin management regimen that maximizes flexibility but does not require very complex calculations of insulin dosing. The study provides a unique outlook on intensive diabetes management; however, larger studies must be conducted before conclusions can be drawn.

Basal-bolus insulin management requires a high degree of DSM and can provide better glycemic control. During periods of glycemic control, persons with DM are able to optimize their social and role functioning. However, mood disturbances and DM-related distress can affect self-management and glycemic control. Depressive symptoms occur in many patients with T1 and T2DM. In a study of adults with T1DM,

increased prevalence of anxiety in women and depression in men was reported (Shaban, Fosbury, Kerr & Cavan, 2006). In patients with T2DM, a meta-analysis estimated the rate of depression to be 17.6 percent, or 1 out of every 6 adults with T2DM (Ali, Stone, Peters & Khunti, 2006). Patients with DM and mood disturbances have decreased glycemic control (Hislop et al., 2008) and self-care (Ciechanowski, Katon, Russo, & Hirsch, 2003). Stress, coping skills, and depressive symptoms have an impact on self-care practices (Peyrot, McMurry & Kruger, 1999) and glycemic control (Ciechanowski et al., 2003) in DM. Pediatric patients with T1DM and depression have poorer glycemic control, adherence, and QOL than their non-depressed peers (Hassan, Loar, Anderson & Heptulla, 2006; Korbel, Wiebe, Berg & Palmer, 2007). Negative stressors and DM-related distress have been linked to decreased self-care in DM (Lloyd, Smith & Weinger, 2005). None of the studies in the literature review examined depressive symptoms, DSM, and QOL; however, Weinger and Jacobson (2001) demonstrated that patients with high DM-related distress have worse glycemic control and self-management, despite interventions ($p<.05$). Depressive symptoms can affect self-management and glycemic control, leading to a decrease in overall functional status. Although the relationships between depression, glycemic control, and functional status are not fully established, it is clear that all contribute to QOL.

Conventional Measurement of QOL

Many studies have been conducted regarding diabetes and QOL, in both T1DM

and T2DM. In the past, QOL was infrequently used as the primary outcome measure but rather a supplemental measure to glycemic control. Over the last decade, QOL has been used as a major study variable, especially in comparisons between CSII and MDI. The relationship between CSII and QOL was examined in a systematic literature review by Barnard, Lloyd, and Skinner, finding no clear QOL benefit from CSII use (2007). A meta-analysis of children with intensively managed T1DM revealed mixed QOL benefits from CSII vs. MDI (Pankowska, Blazik, Dziechchiarz, Szypowska & Szajewska, 2009). In both reviews, the authors noted a problematic lack of consistency in QOL measurement. In many studies, QOL is measured using the Diabetes Quality of Life (DQOL) instrument; however, the DQOL may not be sensitive or specific enough to measure HRQOL in diabetes, especially when related to treatment differences (Speight, J. in Barnard, Lloyd & Skinner, 2007, p.614). The 32 studies of the literature review utilized over 12 different instruments to measure QOL (Table 5). This study is different because it uses multiple components to measure the unique factors that contribute to HRQOL. By measuring QOL comprehensively, differences related to type of diabetes management will be identified.

Table 5. Quality of Life Measures Used by Study Design

QOL Measure	Study Design		
	Cross-Sectional	Longitudinal	RCT
ADDQOL (n=3)		Lowe, 2008	Ashwell, 2008 DAFNE, 2002
DQOL (n=13)	Bruttomesso, 2002 Hoogma, 2004	Bendik, 2009 Chantelau, 1997	DCCT, 1996 Hoogma, 2006

	Zoppini, 2003	Gimenez, 2007 Langewitz, 1997 Weinger, 2001	Jansa, 2006 Kalergis, 2000 Tsui, 2001
DQOL-CTQ (n=1)			Herman, 2005
DQOL-Y (n=2)		Insabella, 2007	Doyle, 2004
DSQOLS (n=3)	EQ1 Study Group, 2008 Scheidegger, 2007	Linkeschova, 2002 Scheidegger, 2007	
DTSQ (n=1 primary, 6 secondary)	EQ1 Study Group, 2008[τ] Hoogma, 2004 [τ] (2nd) Schiel & Mueller, 1999 [τ]		Ashwell, 2008 [τ] DAFNE, 2002 [τ] DeVries, 2002 [τ] Gale, 2000
ITR-QOL (n=1)		Kamoi, 2004	
SF-36 (n=2 primary; n=4 secondary)	EQ1 Study Group, 2008 [τ]	Forlani, 2006 Kalergis, 2000 (MOS) [τ]	DCCT, 1996 [τ] DeVries, 2002 Herman, 2005 [τ]
SF-12 as secondary measure (n=2)		Gimenez, 2007 [τ]	Hoogma, 2006 [τ]
VITA (n=1)	Aberle, 2009		
W-BQ12			DAFNE, 2002 [τ] Gale, 2000
WED (n=2)		Manini, 2007 Forlani, 2006 [τ]	
WHO Well-Being Questionnaire (n=1)	Hoogma, 2004 [τ]		
WHOQOL-BREF (n=1)	Barnard & Skinner,2008		
Unspecified (n=2)	Schiel & Muller, 1999		Pfutzner, 1996

Note. ADDQOL = Audit of Diabetes-Dependent Quality of Life; DCCT = Diabetes Control and Complications Trial; DQOL = Diabetes Quality of Life instrument; DQOL-CTQ = Diabetes Quality of Life—Clinical Trial Questionnaire; DQOL-Y = Diabetes Quality of Life—Youth; DSQOLS = Diabetes-Specific Quality of Life Scale; DTSQ = Diabetes Treatment Satisfaction Questionnaire; ITR-QOL = Insulin therapy-related—Quality-of-Life instrument; QOL = quality of life; SF-12 = Short Form-12; SF-36 = Medical Outcomes Study Short Form-36; RCT = Randomized controlled trial; W-BQ12 = Well-Being Questionnaire 12; WED = Well-Being Enquiry for Diabetics; WHO = World Health Organization; WHOQOL-BREF = World Health Organization Quality of Life-Brief instrument

[τ] Used as secondary measure

Supplemental Literature Review

A supplemental review of the literature was conducted to describe the current status of research related to intensively-managed T2DM and QOL. The detailed search strategy is provided in Appendix A. The review identified 12 articles reporting the findings from nine research projects (Appendix A). The updated search provides a much greater representation of T2DM in intensively-managed DM research; that is, 11 out of 12 studies exclusively enrolled subjects with T2DM. The remaining study was primarily composed of participants with T2DM (80%; Testa et al., 2012). Studies have also improved in methodology: of the nine research studies, five are randomized controlled trials and four are longitudinal. None were cross-sectional. Sample sizes ranged from 34 to 66,726. Of the reviewed articles, eight examined multiple daily injections (basal-bolus; Banerjee, Maji & Baruah, 2013; Hajos et al., 2012; Levin et al., 2011; Opsteen et al., 2012; Peyrot & Rubin, 2011; Shah et al., 2011; Testa et al., 2012; Vinagre et al., 2013), 2 studied CSII (Peyrot et al., 2011 and Rubin et al., 2010), and one reported an intensive management educational program (Hermanns et al., 2012). The remaining study examined a decrease in intensity of insulin management and will be discussed in detail below (Dieuzeide et al., 2014).

All studies examined glycemic control, primarily through A1C, but Testa and colleagues also examined glucose variability (2012). Significant A1C reductions were reported with improved QOL in six articles (Banerjee, Maji & Baruah, 2013; Hajos et al.,

2012; Hermanns et al., 2012; Opsteen et al., 2012; Shah et al., 2011; Testa et al., 2012). Several studies reported hypoglycemia data; none reported associations between hypoglycemia and QOL. Diabetes symptoms were examined in four papers; three studies linked reductions in symptoms with improved QOL (Hajos et al., 2012; Opsteen et al., 2012; Rubin et al., 2010). Depression, anxiety, and DM-distress were measured by Hermanns et al., who reported decreased depressive symptoms in insulin-naïve subjects after three months of basal-bolus insulin therapy (2010).

Similar to the initial literature review, the authors used a large variety of instruments to study QOL. QOL instruments included the DQOL (n=4), SF-12 or SF-36 (n=3), EQ-5D^{TM} (n=6), the WHO-5 Wellbeing Index (n=1), and an author's own instrument (n=1; Testa et al., 2012). The diversity of measures used makes comparison difficult; however, the majority of the articles (n=7) revealed significantly improved QOL (Appendix A). Lack of QOL effects could be due to small sample sizes (n=37, Vinagre et al., 2013; n=54, Peyrot et al., 2011) or using instruments with lower sensitivity to QOL in DM (DQOL, Levin et al., 2011; SF-36, Peyrot & Rubin, 2011). It should be noted that no studies showed decreased QOL after beginning intensive insulin management.

One article of the literature review had unique findings. Dieuzeide and colleagues conducted a sub-study (n=1024) of the data from the A1chieve study, a large multi-national trial of analog insulin initiation (n=66,726). In the sub-study, patients on multiple daily injections (basal-bolus) changed to analog premixed insulin (basal only;

Dieuzeide et al., 2014). Significantly improved QOL was found with this less intensive insulin management strategy ($p<.001$). However, it should be noted that over 88% of subjects in the study were using non-analog insulin (Regular and/or NPH) prior to study enrollment. Use of analog insulin has been linked to improved QOL (Hartman, 2008). The sub-study subjects also experienced significantly improved glycemic control (mean A1C decrease by 2%, $p<.001$) and less hypoglycemia, especially in the baseline NPH group ($n=770$; $p<.001$). Both of these factors may be confounding variables in the analysis of insulin management strategy and QOL. Finally, the Dieuzeide study suffered from large sample attrition as 491 subjects (48%) were lost to follow-up. Attrition greater than 20% may affect generalizability and internal validity (Polit & Beck, 2004). The findings of this study must be considered carefully and should be replicated before making final conclusions regarding QOL in intensive insulin management.

CHAPTER THREE

METHODOLOGY

The study was an observational study to examine quality of life in patients with type 2 diabetes, according to type of glycemic management. The aims are as follows: (1) to describe the HRQOL of persons with T2DM according to type of glycemic management [Oral meds only, Insulin once or twice daily (basal only), Insulin three or more times daily (basal-bolus)], (2) to determine if HRQOL of persons with T2DM differs depending on type of glycemic management, and (3) To determine if type of glycemic management is predictive of HRQOL after controlling for covariates (i.e., age, gender, complications of DM, duration of DM).

Design

The study was a cross-sectional, observational study exploring differences in HRQOL outcomes in patients with type 2 diabetes, based on type of diabetes management. The study attempted to determine whether the type of insulin management has a significant impact on HRQOL in persons with T2DM.

Setting

The study was conducted through the mail, with recruitment of participants through clinic, electronic, and community sources. Data collection occurred over a

period of 15 months (January 2012 to March 2013). All participants lived within the United States.

Sample

Inclusion Criteria

All adults 18 years and older who reported that they had "adult onset" or "type 2 diabetes" for at least six months and could read, write, and speak English were eligible for the study. Participants had to have been taking antihyperglycemic medications at least daily (insulin or oral) and be using the same medication regimen (insulin or oral) for the past three months. The inclusion criteria of having diabetes for at least six months was selected as it is the time where the maintenance phase of treatment occurs with a new health behavior (Prochaska & Velicer, 1997).

Exclusion Criteria

Patients were excluded if they had the following co-morbid diagnoses with potential to impact HRQOL: major psychiatric disorders (not including depression), dementia, Alzheimer's, HIV, cancer (requiring chemotherapy or radiation in the last 3 years), or other chronic conditions that may impact QOL (e.g., sickle cell disease, multiple sclerosis, fibromyalgia). Patients reporting current pregnancy were excluded from the study. The participant screening tool is shown in Appendix B.

Sample Size Estimation

Power analyses were completed using G*power version 3.1.2 (F. Faul,

Universität Kiel, Germany; Faul, Erdfelder, Lang & Buchner, 2007). As the three research aims have different statistical analyses, three preliminary power analyses were conducted using G*power, to obtain minimum sample size for the study. Medium effect sizes were chosen for the power analyses; values for medium effect size were provided by G*power. Alpha was set at 0.05 for all power analyses. For a fixed-effects, one-way ANOVA (3 groups), a total sample size of 159 is required to achieve 80% power with an effect size of F=0.25. For the special effects MANOVA with interactions, a sample size of 73 is necessary to achieve an F^2 of 0.25 at 95% power with four groups, three predictors, and one response variable. For a fixed-model multiple regression, assuming a R^2 deviation from zero, a sample size of 138 subjects is required to obtain an F^2 of 0.15 at 95% power with five predictors. Details of the power analyses are given in Table 6. Given that 159 is the maximum number of persons needed to meet the aims, and that a maximum of missing or incomplete data could be approximately 25 percent, the enrollment goal of the study was 199 total subjects.

Table 6. Power Analysis: Sample Size Calculations Based on Statistical Test

Statistical Test	Effect size	Alpha	Power	Groups	Predictors	Response Variables	N required
ANOVA	F=0.25	0.05	0.80	3	n/a	n/a	159
MANOVA	F^2=0.25	0.05	0.95	4	3	1	73
Multiple regression	F^2=0.15	0.05	0.95	n/a	5	n/a	138

Data Collection

Recruitment

Participants were recruited through one of seven methods: (1) letter mailed to persons with diabetes who have agreed to be informed of diabetes studies through a National Institute of Health (NIH)-funded study of women with T2DM informing them of the proposed study (Appendix C), (2) flyers posted at outpatient clinics in the Midwest suburbs of Chicago (Appendix D), (3) electronic flyers posted to websites of interest to people with diabetes (Table 7), (4) Chicago Diabetes EXPO (April 14, 2012, at McCormick Place), (5) study notification (containing electronic flyer) sent to all staff members at a Chicago-area University Medical Center via Novell Web Access e-mail broadcast, (6) community posting of flyers in churches, park districts, coffeehouses, etc. and (7) snowball recruitment (study contact information was given by an enrolled subject to a friend/family member who then initiated contact with the primary investigator). The query letter and flyer directed participants to contact the primary investigator (Sandra McCormick) via phone call. Within 48 hours, calls were returned to explain the study, determine agreement for participation, and screen for eligibility. Subjects meeting the inclusion criteria were asked for their mailing address and the best way to contact them (e-mail or phone). Subsequently, a study packet was sent to their mailing address, including a pre-addressed, stamped envelope for return of study materials.

Table 7. Diabetes-Related Websites for Study Recruitment

Website Name	Type	Website Address
American Diabetes Association: Chicago	Social media site	http://www.facebook.com/chicagoada
American Diabetes Association	Support Forum "Adults Living with Type 2"	http://community.diabetes.org/t5/Adults-Living-with-Type-2/bd-p/Adults-Living-with-Type-2
Dailystrength.org	Message Board "People with Type 2 Diabetes"	http://www.dailystrength.org/c/Diabetes-Type-2/support-group
Diabetes Blog Network	Diabetes blogs	http://www.diabetesblognetwork.com/
Diabeticconnect.com	Discussion boards	http://www.diabeticconnect.com/
Facebook	Social media site	http://www.facebook.com/T2Diabetes

Procedure of Data Collection

The study packet included a cover letter describing the study, the process for participation, and instructions to contact the study investigator, Ms. McCormick, with any questions (Appendix E). The letter stated that participation would take about 90 minutes of their time. The letter delineated the three steps of participation: (1) completion of an 18-page questionnaire booklet, which includes seven study tools, (2) performance of a fingerstick A1C test kit with instructions, and (3) return of the completed materials by U.S. Mail in the provided pre-paid envelope. The envelope was pre-addressed to the study investigator's Post Office Box. Each questionnaire booklet and A1C test kit had a pre-assigned ID number. Upon receipt of the materials, the study

investigator sent the A1C blood spots for testing. Data collection occurred concurrently among subjects.

Measurements

All additional study variables were assessed using established, psychometrically validated instruments as discussed below. The measurements for the respective variables are described below using the framework used to guide this study (Table 8).

Table 8. Variables and Measurements of Study

Revised Wilson and Cleary HRQOL Concepts	Study Variable	Measurement Tool
Individual Characteristics	Demographics	Questionnaire
Environmental Characteristics	Access to diabetes care	Brief-CIRS item
	Social Support	Brief-CIRS
Biological function	Insulin dosing frequency	Questionnaire
	Co-morbidities/complications	Questionnaire
	Glycemic control	A1C (Reli On, Heritage Labs)
Symptoms	Hypoglycemia	DSC-R & self-report items
	Hyperglycemia	DSC-R
	Mood	Well-Being Questionnaire 12
	Pain	DSC-R
	Vision	DSC-R
	Activity tolerance	DSC-R
Functional Performance	Social Functioning (Mental Health Summary)	SF-12 Health Survey (version 2): MCS
	Role functioning (Physical Health Summary)	SF-12 Health Survey (version 2): PCS
	Diabetes Self-Management	Self Care Inventory-Revised
General health perception	Overall health	General health item of SF-12 (v2)
	Acceptance of diabetes	Appraisal of Diabetes Scale
Quality of life	Perceived HRQOL	Quality of Life Index

Note. HRQOL = Health-Related Quality of Life; CIRS = Chronic Illness Resources Survey; A1C = Glycosylated Hemoglobin; DSC-R = Diabetes Symptom Checklist-Revised.

Instrument costs and access are noted in Table 9.

Table 9. Study Instruments: Costs, Access, and Websites

Instrument Name	Cost	Need Permission	Website
Brief Chronic Illness Resource Survey	Free	No	https://www.gem-beta.org/public/MeasureDetail.aspx?mid=116&cat=2&mode=m
Diabetes Symptom Checklist-Revised	Free	No	www.vumc.com/afdelingen/diabetes-psychology/Measures
Well-Being Questionnaire 12	$ [a]	Yes [a]	http://www.healthpsychologyresearch.com/Admin/uploaded/Summary/w-bq12%20summary%20rev_15jan07.pdf
SF-12 Health Survey, version 2	$ [b]	Yes [b]	http://www.sf-36.org/tools/sf12.shtml
Self-Care Inventory-Revised	Free	Yes [c]	http://www.psy.miami.edu/faculty/alagreca/SCI_manual_2004.pdf
Appraisal of Diabetes Scale	Free	No	www.musc.edu/dfm/RCMAR/DiabetesTools.html
Quality of Life Index: Diabetes Version	Free	Not for non-profit	www.uic.edu/orgs/qli

[a] Student licensing agreement received. No cost for unfunded students.

[b] Student license agreement received. No cost for unfunded students.

[c] Permission received from copyright holder Dr. LaGreca.

Individual Characteristics

Individual characteristics were assessed via demographic questionnaire (Appendix F). The questionnaire also assessed insulin dosing frequency and presence of co-morbidities and diabetes complications (Appendix F). Additional single items were scored using Likert-type scoring, ranging from “not at all” to “a great deal”.

Biologic Function

Biologic function was assessed by glycemic control, diabetes complications, and insulin dosing frequency. For glycemic control, hemoglobin A1C was measured using the Reli-On Home A1C test (Heritage Labs International, Olathe, KS), an at-home fingerstick test kit that uses filter paper and postal submission to their laboratory (Heritage Labs, n.d.). The Reli On Home Diabetes A1C Test is manufactured and tested by Heritage Labs International (Olathe, KS). Designed for home use by retail consumers, the test uses fingerstick blood sampling on filter paper to provide A1C assessment. The sample is submitted by mail to the laboratory. The CLIA-certified results are available online within 3 business days or can be mailed directly to the patient and/or researcher (CLIA Registration number 17D0943396). Use of capillary blood filter paper A1C testing has been compared to venous laboratory testing (r=0.987) and is considered a valid method of measuring A1C, with between-filter coefficient of variation of 1.8 percent (Fokkema et al., 2009). Heritage Labs reports the air-dried filter paper blood specimens are stable for at least 30 days at room temperature (Heritage Labs, n.d.). Precision of the Reli On has been demonstrated using within-assay variability at four levels of A1C, with a coefficient of variation less than two percent (Table 10). Linearity was established in a full range of A1C values (3.10 to 16.23) with a maximum deviation of 1.3 percent. Accuracy of the Reli On was verified using comparison of samples with whole blood A1C samples in a diverse range (linear regression $R^2 = 0.9979$; Heritage Labs, n.d.).

The Reli On Home Diabetes A1C kit provided a simple, valid, and accurate method of measuring A1C in this study.

Table 10. Within-assay Variability: Reli On® / Appraise® Hemoglobin A1C Test

Mean Hemoglobin A1C (%)	Standard Deviation	Coefficient of Variation (%)
5.6	0.1	1.8
7.3	0.0	0.0
8.7	0.0	0.0
10.4	0.0	0.0

Specimens tested 20 times
From *Appraise® Hemoglobin A1C Test*, Heritage Labs, Olathe, KS

Environmental Characteristics

Access to diabetes care. Access to care was measured using a single item from the Brief-CIRS instrument (discussed below), "Have you had health insurance that covered most of the costs of your medical needs including medicine?" (Glasgow, Toobert, Barrera & Strycker, 2004).

Social support. This was measured using the Chronic Illness Resources Survey. The Chronic Illness Resources Survey (CIRS) was developed to provide a measurement of socio-ecological support for chronic disease self-management (Glasgow, Strycker, Toobert & Eakin, 2000). The original instrument was 64 items and had subscales of personal, family/friends, physician/health care team, neighborhood/community, organizations, work, media & policy. Items were scored on a Likert-type scale (1=not at all to 5=a great deal); means were calculated for subscale scores. High scores denote high support for disease self-management. The original 64-item instrument was reduced to 29 items and then to 22 items to create the Brief-CIRS, without sacrificing

internal consistency (α = 0.82) or test-retest reliability (r=0.70; Glasgow et al., 2004). Some individual subscales from the Brief-CIRS are not as valid as the original CIRS (α=0.40-0.55; Glasgow et al., 2004); therefore, the subscales of media & policy, organizations, and neighborhood/community were not used individually in this study. The Brief-CIRS was administered in original format; however, items from the subscales in question were used only to calculate the overall score. Remaining subscales of the Brief-CIRS have acceptable internal consistency (e.g., personal, family/friends and physician/health care team). Convergent validity was tentatively established for the Brief-CIRS total score and subscales using correlation with existing measures of social support (Interpersonal Support Evaluation Checklist), and healthful eating and activity patterns (Social Support for Eating Habits and Exercise Survey; r=0.17 to 0.56; Glasgow et al., 2004). The Brief-CIRS provided a multidimensional assessment of environmental support for the study (Appendix F). For the present study, the Cronbach's alpha was 0.810, indicating acceptable reliability (Polit & Beck, 2004).

Symptoms

Hypoglycemia. Frequency of hypoglycemia was assessed using two self-report questions developed by the author: (1) in the last week, how many times have you experienced hypoglycemia? and (2) in the past year, how many times have you experienced hypoglycemia requiring the help of another person? (Appendix F).

Diabetes symptoms. Designed to measure the symptoms experienced by patients with T2DM, the Diabetes Symptom Checklist-Revised (DSC-R) is an instrument which quantifies the presence and perceived burden of physical and psychological symptoms of diabetes and its complications (Grootenhuis, Snoek, Heine & Bouter, 1994). The 34-item questionnaire allows respondents to report the presence (or absence) and rate the degree of discomfort the symptom has caused using Likert scaling (from 1="not at all troublesome" to 5="extremely troublesome"). The DSC-R explores symptoms from eight dimensions: hyperglycemia, hypoglycemia, ophthalmology, cardiology, neuro-sensory, neuro-pain, psychology-cognitive, and psychology-fatigue. Total scores and subscale scores range from zero to five, with higher scores indicating greater diabetes-related symptoms.

Originally developed in 1994 from literature reviews and consultation with physician experts, the DSC was revised in 2009 to clarify scaling and presence of symptoms (Arbuckle et al., 2009). Internal consistency of the DSC-R was measured by Cronbach's alpha ranging from 0.76-0.95 for all dimensions (α=0.69-0.87 subscales, 0.95 overall; Arbuckle et al., 2009). Test-retest reliability was established (r=0.79-0.94) and confirmatory factor analysis verified validity of subscale dimensions (GFI= .9022; Arbuckle et al., 2009). Concurrent validity was documented by correlations between DSC-R scores and SF-36 scores (r=-0.22 to -0.69; Arbuckle et al., 2009). The DSC-R measured the importance and presence of diabetes-related symptoms for the subjects

in the study (Appendix F). For the present study, the Cronbach's alpha was 0.942, indicating a very reliable instrument.

Mood symptoms. The Well-Being Questionnaire 12 (W-BQ12) was used to measure psychological well-being (Bradley, 2007). The twelve-item scale is a revision of the W-BQ22, which was developed from interviews of clinicians and patients with IDDM (Garratt et al., 2000). The W-BQ12 is a brief assessment of positive and negative psychological well-being. Each of the 12 items is scored from 0 ("not at all") to 3 ("all the time"; Bradley, 2007). The first three subscales (negative well-being, energy, positive well-being) ranging from 0 to 12 points are totaled to obtain the general well-being, or summary score, of 0 to 36 points (Bradley, 2007). Higher scores represent greater well-being. The negative well-being subscale is negatively worded and reverse-scored in the summary total. The W-BQ12 has been successfully used in subjects with IDDM and DM treated with oral medications (Garratt et al., 2000).

Factor analysis of the W-BQ12 supported the three-factor solution (≥90% of variance explained; Pouwer, Snoek, van der Ploeg, Ader & Heine, 2000). Item-total correlations were acceptable (0.38 to 0.75; Pouwer et al., 2000). Internal consistency, as measured by Cronbach's alpha, ranged from 0.73 (negative well-being) to 0.91 (general well-being; Pouwer, van der Ploeg, Ader, Heine & Snoek, 1999). Test-retest reliability was 0.66 to 0.83 over two months (Pouwer et al., 1999). Construct validity was demonstrated by correlations between negative well-being and the following

instruments: the Hospital Anxiety and Depression Scale (r=0.54-0.60), the State/Trait Anxiety Inventory (r=0.63-0.76), and the Center for Epidemiological Studies Depression Scale (r=0.67). Furthermore, general well-being correlated positively with the SF-36 (r=0.22-0.49) and negatively with the Center for Epidemiological Studies Depression Scale (r= -0.80; Pouwer et al., 1999). In conjunction with the psychological dimensions of the DSC-R, the W-BQ12 measured psychological well-being in study subjects (Appendix F). Diagnoses of depression or anxiety were not made. For the present study, the Cronbach's alpha was 0.883 for general well-being. For the subscales, the Cronbach's alpha was 0.746 for negative well-being, 0.796 for energy, and 0.829 for positive well-being.

Functional Performance

Social and role function. Social and role functioning were assessed using the SF-12 Health Survey (version 2). The SF-12 (v2) is an abbreviated version of the SF-36, a measure of physical and mental functional health status (Ware, Kosinski, Turner-Bowker & Gandek, 2002). The SF-12 is widely used in health care research and has been used with adult patients with a variety of medical diagnoses, including DM. Each of the 12 questions is scored on a 5-point Likert-type scale with higher scores equaling better functioning. The SF-12 has eight subscales: physical functioning, role-physical functioning, body pain, general health, vitality, social functioning, role-emotional functioning, and mental health. Scoring is provided for each subscale and for both a

physical and mental composite score. The SF-12 has acceptable test-retest reliability (0.76 – 0.89; Ware et al., 2002). The instrument has high internal consistency as measured by Cronbach's alpha of 0.80 to 0.90 for composite scores (Ware et al., 2002). Subscale scores are less reliable, with Cronbach's alpha ranging from 0.66 to 0.90 in the general population (Ware et al., 2002). For this study, only the physical and mental composite scores of the SF-12 were used to represent functional status. The SF-12 is shown in Appendix F. Instrument reliability in this study was demonstrated with a Cronbach's alpha of 0.815 (physical composite score) and 0.792 (mental composite score).

Diabetes self-management. Another dimension of functional performance, diabetes self-management, was assessed using the Self Care Inventory-Revised (SCI-R). The Self Care Inventory was originally developed in 1988 to measure patients' perceptions and performance of self-care activities as related to DM (LaGreca et al. in Weinger, Butler, Welch & LaGreca, 2005). It was later revised to reflect changes in DSM practice. The 15-item questionnaire includes assessment of dietary practices, blood glucose monitoring, medication administration practices (including insulin), exercise, hypoglycemia treatment, and basic diabetes self-care. Items are rated on a Likert scale of "never" to "always", with the option of "not applicable" for insulin, pills, and ketone testing. Items are averaged and converted to a scale of 0-100 points. Tested in patients with T1 and T2DM, reliability was established with internal consistency of $\alpha = 0.87$.

Concurrent validity was established with an existing measure of diabetes self-care (r=0.63); convergent validity was documented via negative correlation with diabetes-related distress (r=-0.36; Weinger et al., 2005). Principal components analysis confirmed the single-scaling of the measure (Eigenvalue=4.5 explained 38% variance in n=199 subjects with T2DM, factor loadings 0.44 to 0.79); responsiveness was established by documented improvement in SCI-R scores after receiving DSM education (Weinger et al., 2005). In this study, the SCI-R measured subjects' performance of DSM activities (Appendix F). For the present study, Cronbach's alpha was 0.651, indicating sub-optimal reliability for the overall scale. The Cronbach's alpha was recalculated without two items ("check ketones when glucose level is high" and "carry quick acting sugar to treat low blood glucose"). The SCI-R was originally developed for patients with T1DM. Patients with T2DM are less likely to experience hypoglycemia and be instructed to check ketones. In subjects taking oral medication only, the recalculated Cronbach's alpha was 0.714. The Cronbach's alpha was 0.713 for subjects on insulin, indicating acceptable reliability of the measure in both groups.

General Health Perceptions

To assess for subjects' acceptance of diabetes, the Appraisal of Diabetes Scale (ADS) was used. The ADS is a seven-item questionnaire that can be completed within five minutes (Carey et al., 1991). Originally tested on 200 men with diabetes (n=132 with IDDM), the ADS was designed as a single factor scale to evaluate personal beliefs

about DM and its impact. The questions assess control, uncertainty, coping, effect of diabetes on life goals, predictive view of diabetes and degree of distress caused by diabetes (Garratt, Schmidt & Fitzpatrick, 2002). A higher ADS score indicates a greater negative impact of DM or less personal acceptance of the disease. Internal consistency was measured 0.73 by Cronbach's alpha; reliability was measured by a test-retest correlation of 0.85-0.89 (Carey et al., 1991). Validity was established via correlation with existing measures: Diabetic Daily Hassles Scale (r=0.59), Diabetes Health Belief Questionnaire (r=0.31-0.42) and the Perceived Stress Scale (r=0.49; Garratt, Schmidt, & Fitzpatrick, 2002). Principal components analysis confirmed single-scaling of the ADS (Eigenvalue=2.73 explained 39% variance, factor loadings 0.424 to 0.752; Carey et al., 1991). The ADS provided a quantitative measure of subjects' personal models and acceptance of diabetes for this study (Appendix F). For the present study, Cronbach's alpha was 0.820, indicating acceptable reliability.

Quality of Life

Perceived health-related quality of life was assessed by the Quality of Life Index: Diabetes Version. The Ferrans and Powers Quality of Life Index (QLI) was developed originally in 1984 as a measure of multidimensional QOL (Ferrans & Powers, 1985). Respondents rate their satisfaction with (1=very dissatisfied to 6=very satisfied) and the importance of (1=very unimportant to 6=very important) QOL-related items using a Likert scale. Satisfaction ratings are weighted by importance to calculate an overall

score and subscores for four domains: health and functioning, psychological and spiritual, social and economic, and family. Possible total scores range from zero to 30. The mean score of 23.00 represents the normal population and 20.56 represents persons with diabetes. From the generic version, additional versions of the QLI have been created for a variety of disease populations, including arthritis, cancer, cardiac, chronic fatigue, DM, dialysis, epilepsy, renal and liver transplant, multiple sclerosis, pulmonary, spinal cord injury, and stroke (Ferrans & Powers, n.d.a). The diabetes version has 34 items and is available in five languages including English. It is written at the fourth-grade reading level and can be self-administered in approximately ten minutes. Construct validity of the QLI was established via strong correlations (r=0.61-0.93) with the Campbell, Converse, and Rodgers measure of life satisfaction (1976) and factor analysis confirming the subscales and explaining 91 percent of the variance (Ferrans & Powers, 1992; Ferrans & Powers, n.d.b) The QLI has demonstrated sensitivity to change (DeSouza & Nairy, 2003; Hathaway et al., 1994a; Hathaway et al., 1994b) and test-retest reliability (r=0.87 for 2 week interval; Ferrans & Powers, 1985). Both total and sub-scales have demonstrated excellent internal consistency, with a Cronbach's alpha ranging from 0.85 to 0.97 (DeSouza & Nairy, 2003; Ozer & Efe, 2006). Although the QLI has not been used in any published studies of DM managed with basal-bolus insulin, the QLI-Diabetes version has been used in four studies of patients with T2DM (Arun et al., 2008; DeSouza & Nairy, 2003; Hu, Wallace & Tesh, 2010; Quinn, 1996) and

one study of patients with either T1 or T2DM (Lewko, et al., 2013; see Table 11). Also, the QLI-generic version was used in a study of patients with T1DM undergoing transplantation (Hathaway et al., 1994a; Hathaway et al., 1994b; see Table 11). Although the QLI-Diabetes version has not been used with patients using intensive insulin management for their DM[1], it has well-established reliability and validity and is a promising multidimensional tool for QOL assessment in this population. The QLI: Diabetes Version provided a multidimensional measurement of HRQOL in study subjects (Appendix F). For the present study, Cronbach's alpha was 0.949 for overall quality of life and for the subscales was 0.914 for health and functioning, 0.908 for psychological and spiritual, 0.773 for social and economic, and 0.714 for family.

[1] As of 6/1/2014, per searches of OVID, PubMed, and CINAHL, no studies were found using the QLI in DM managed with basal or basal-bolus insulin.

Table 11. Studies Using the Quality of Life Index

Authors	Design	Setting	N	Mean Age	% Female	DM type	Duration (months)
QLI: Diabetes Version							
Arun et al. 2008	RCT: role of pharmacist	Rural India: outpatient	154	58	55	2[a]	5
DeSouza & Nairy, 2003	Longitudinal: Nurse-directed intervention	India: outpatient	60	65% are 41-60	28	[b]	2
Hu, Wallace & Tesh, 2010	Cross-sectional: Diet, Exercise, Obesity as QOL predictors	Southeastern US: outpatient	59	49	68	2[c]	0
Lewko et al. 2013	Cross-sectional: hand neuropathy, function as related to QOL and depression	Poland: inpatient	71	55	52	1 or 2[d]	0
Quinn, 1996	RCT: impact of exercise	Urban US: outpatient	10	60	50	2[e]	2
QLI: Generic Version							
Hathaway et al. 1994a; Hathaway et al., 1994b	Longitudinal: Pre-Post Transplant (Kidney only or kidney-pancreas)	US: Large medical & transplant center	30	40	60	1	6

Note. DM = diabetes mellitus; RCT = randomized controlled trial; QOL = quality of life

[a] Controlled by oral medications only

[b] Type of DM not specified; 78% of sample treated with oral medications and diet

[c] Majority of subjects took oral medications; 25.6% on insulin

[d] Majority of subjects (70%) had T2DM. No medication regimen(s) reported

[e] Controlled by diet or oral medications

Data Analysis

Data Entry and Cleaning

De-identified data was entered directly from questionnaire booklets into an SPSS file (SPSS Windows Version 20.0, SPSS, Chicago, IL). Data cleaning was performed using frequency distributions (categorical and interval variables) and descriptive statistics (continuous variables) to verify freedom from data entry errors. Missing data was reported using descriptive statistics and is reported in Chapter 4. Demographic information was analyzed using descriptive statistics.

Analysis per Aims

Data analysis for each aim included:

Aim 1: To describe the HRQOL of persons with T2DM according to type of glycemic management. Analysis: Patients were divided into groups based on medication dosing frequency [Oral meds only, Insulin once or twice daily (basal only), Insulin three or more times daily (basal-bolus)]. Descriptive statistics were used to report total and subscale QOL and to describe the sample.

Aim 2: To determine if HRQOL of persons with T2DM differs depending on type of glycemic management. Analysis: ANOVA/MANOVA. Subjects were divided into three groups based on the type of glycemic management: oral meds only, insulin once or twice daily (basal), insulin three or more times daily (basal-bolus). The dependent variable, quality of life, was represented by QLI scores. Group differences in QLI scores

were examined using Analysis of Variance (ANOVA), with post-hoc testing planned to establish pair-wise group differences (Munro, 2005).

To examine complex interactions that may confound QOL measurement in this population, Multifactorial Analysis of Variance (MANOVA) was used. In the MANOVA, the variables tested included: type of glycemic management (oral, basal insulin, or basal-bolus insulin), glycemic control (Hemoglobin A1C), diabetes symptoms, mood (psychological well-being), diabetes self-care, acceptance of diabetes, and quality of life. These variables were chosen according to the study model, which represents subjects' overall adjustment to life with diabetes. Sources of variation in the MANOVA included main effects as well as interactions between variables. Analysis of two- and three-way interactions can provide a greater understanding of interrelation between complex variables that can affect a dependent variable (Munro, 2005).

Aim 3: To determine if type of glycemic management is predictive of HRQOL after controlling for covariates (age, gender, complications of DM, duration of DM). Analysis: Multiple Regression. Multiple regression is a statistical technique which uses several independent variables to predict a dependent variable in an equation format (Munro, 2005). Three multiple regressions were performed. In the first regression, predictor variables such as hemoglobin A1C, diabetes symptoms, diabetes self-care, general well-being, and acceptance of diabetes were entered with QLI scores in a simultaneous manner to obtain the prediction equation. In the second regression, the

same predictor variables were entered in a forward method to predict QLI scores. All variables' beta weights were examined for significance ($p \leq .05$) before inclusion into the prediction equation (Munro, 2005). Variables that do not contribute a significant R^2 change to the equation were not included. Finally, the predictor variables of general well-being and diabetes self-care were used in a multiple regression (forward method) followed by forced entry of the moderation effect between the two predictors of QOL. Details of the analyses are discussed in Chapter Four.

Human Subjects Protection

Human subjects procedures included the telephone screening process, answering of the questionnaire booklet, and the performance of fingerstick capillary blood sampling on filter paper for A1C testing. The study included both male and female adult patients with T2DM. Patients with major psychiatric disorders (not including depression), dementia, Alzheimer's, HIV, cancer (requiring chemotherapy or radiation in the last 5 years), sickle cell disease, fibromyalgia, or active pregnancy were excluded from the study, due to the impact of these conditions on QOL and possible confounding effects. Persons who were unable to read, write, and speak English were excluded from the study. As the study was conducted by a graduate student with limited funding, it was beyond the scope of this study to provide interpretive services for potential subjects.

To ensure protection against risks, all data was collected from de-identified questionnaire booklets and from fingerstick A1C card, resulted from the company using a unique identification number assigned by the study investigator.

Potential risks included breach of confidentiality and infection at fingerstick site. The above potential risks were judged as unlikely to occur as precautions to ensure confidentiality were taken. The list of eligible subjects and recorded data is kept in a locked file drawer. Completed instruments fingerstick card (sent through the mail), and results do not have any identifying information. Only research team members have access to this data. Pregnant women and children were not included in this research study. To prevent infection, explicit directions on how to perform an aseptic fingerstick bloodspot sample were provided; however, since most subjects routinely perform self-monitoring of blood glucose, this fingerstick sample was a familiar experience. The potential risks were minimal and precautions to prevent breach of confidentiality continue with the de-identification and aggregation of all data. For this study, there was no breach of confidentiality or infection known to this investigator.

There were no direct benefits from participation in the study; however, the results of the study may help caregivers to better understand the experience of persons living with T2DM which may help them to provide better care. All participants were sent a copy of their A1C results by mail. Subjects who completed the study received a $10 gift card as an honorarium for their time.

CHAPTER FOUR

RESULTS

The purpose of the study was to examine quality of life in patients with type 2 diabetes according to type of glycemic management. Description of the sample is provided via descriptive statistics. The aims of the study were as follows: (1) to describe the HRQOL of persons with T2DM according to type of glycemic management [Oral meds only, Basal insulin only (once or twice daily), Basal-bolus insulin (three or more times daily)], (2) to determine if HRQOL of persons with T2DM differs depending on type of glycemic management, and (3) to determine if type of glycemic management is predictive of HRQOL after controlling for covariates.

Recruitment Information

One hundred thirty eight people called the study voice mail (See Figure 2 for enrollment diagram). Of these, 120 met criteria and agreed to be enrolled in the study. Of the 120 enrolled, 107 subjects completed and returned their study packets. The final sample was 107 adults (73 on oral medications only, 15 on basal insulin, 19 on basal-bolus insulin). Sources of recruitment for the sample are shown in Table 12. The most common sources of recruitment were a database of local patients who had agreed to be notified of diabetes studies (43%) and internet flier posting (Facebook; 39%).

Figure 2. Enrollment Diagram

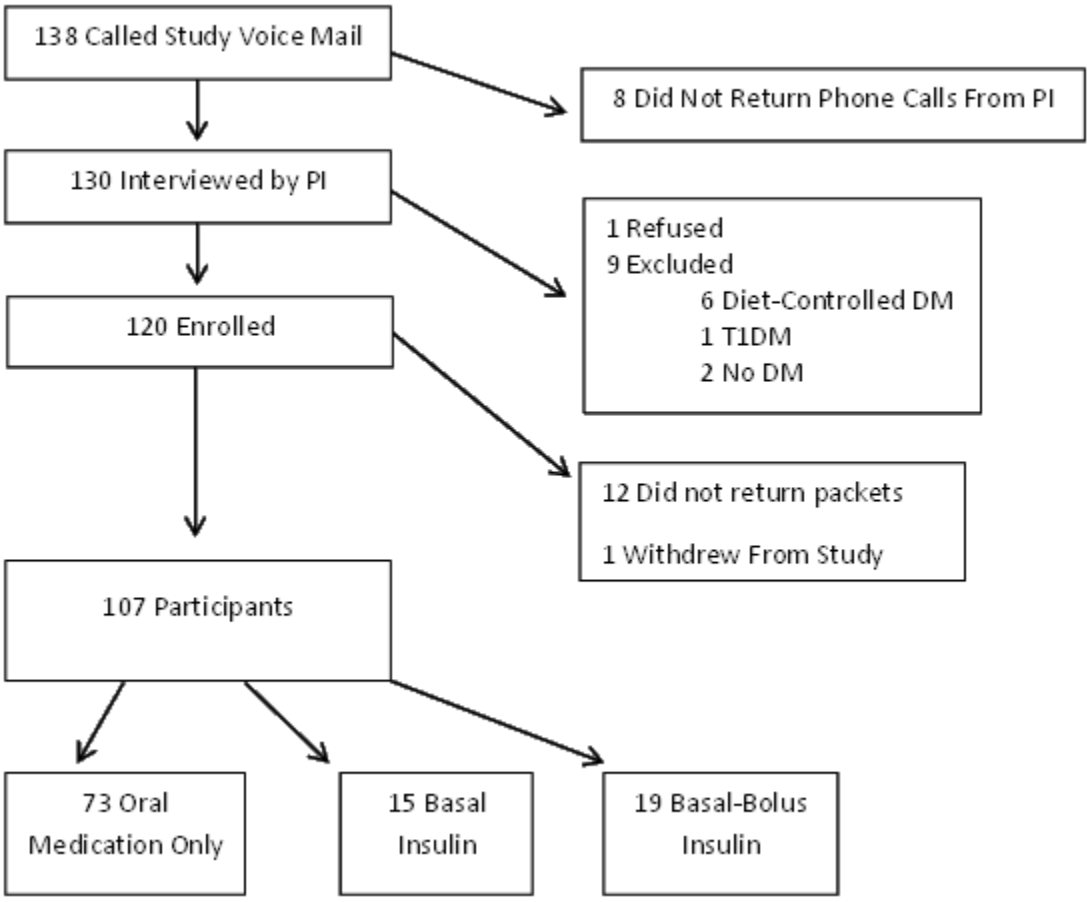


Table 12. Recruitment Sources

Recruitment Source	Final Sample		Excluded/Non-respondents	
	Frequency	Percent	Frequency	Percent
Database	46	43.0	12	38.7
Expo	3	2.8	3	9.7
Facebook	39	36.4	7	22.6
LUMC Diabetes	4	3.7	2	6.5
Snowball	9	8.4	4	12.9
Diabetic Connect	2	1.9	3	9.6
Staff email LUMC	4	3.7	0	0
Total	107	100.0	31	100.0

Missing Data

Missing data was limited because all booklets were checked for completion upon return. All subjects with missing data had agreed to be contacted by the primary investigator in case of questions regarding survey completion. Subjects were contacted by telephone and provided information regarding missing items (i.e., skipped accidentally or on purpose). Purposeful blank items were accepted. There was less than one percent of unexpected missing data (total 21 items in entire sample). Some data was expected to be missing; for example, the majority of the sample was retired, work-related items were not completed by these subjects. In most cases, expected missing data did not affect scoring because authors of the study instruments had provided for missing data while designing the scoring metric (CIRS, QLI). Replacement of data was done as reported in Appendix G. When data could not be deductively imputed without excessive risk of distorting relationships between variables, it was not replaced. Data was not replaced in the following items: income (7.5%), history of eye problems (<1%), work-related questions (34-67%), children/sex life/spouse (9-20%). Details are provided in Appendix G.

In nine cases, the hemoglobin A1C was unable to be processed by the laboratory due to insufficient specimen quantity. These subjects were all re-contacted to request an additional fingerstick specimen; of the three subjects reached, all returned a second

specimen for successful testing. Six subjects were lost to follow-up for obtaining a second sample of testing (5.6%).

Expected missing data included employment- and family-related items. Both the CIRS and QLI had expected missing data related to employment. The majority of subjects (67.3%) reported not currently working outside the home. The QLI also had expected missing data related to family. Forty-two percent of subjects reported their marital status as single, divorced, separated, or widowed. Also, 9.3% of subjects stated no children. These items were accepted as blank and not replaced. Total and most subscale scores were successfully calculated without the expected missing items. The exception was the CIRS work subscale, which could only be calculated for 35 subjects.

Characteristics of Overall Sample

The majority of the sample was female (75.7%), non-Hispanic (96.2%), Caucasian (84.1%), married (57.9%), retired (52.3%), and had an average age of 64 years. Demographics of the sample are provided in Table 13. Subjects were divided into groups based on type of insulin management (oral medication only, basal insulin, basal-bolus insulin). Chi-square tests did not detect differences between groups in gender, ethnicity, income, education, and employment. Using chi-square, significant differences were found between groups in race and marital status. White subjects were most likely to be on oral medication only; black subjects were equally likely to be on oral medication or basal insulin (χ=27.050, $p<.01$). Subjects using basal-bolus insulin were

89.5% Caucasian. Subjects who were never married were most likely to be using basal insulin; subjects of every other marital status were most likely to be taking oral medications only (χ=30.828, p<.001). Subjects on basal insulin were slightly younger than subjects on oral medications only or basal-bolus insulin; however, per one-way ANOVA, this was not statistically significant.

Table 13. Description of the Sample

Variable		Total Sample N=107 (%)	Oral Medication N= 73	Insulin	
				Basal N=15	Basal-Bolus N=19
Age	Mean ± SD	63.8 ± 11.8	65.3 ± 11.6	57.4 ± 12.2	63.1 ± 11.2
	Range	27-87	27-87	36-82	42-83
Gender	Female	81 (76%)	55	14	12
	Male	26 (24%)	18	1	7
Ethnicity	Hispanic	4 (4%)	3	0	1
	Non-Hispanic	103 (96%)	70	15	18
Race**	White	90 (84%)	65	8	17
	Black	12 (11%)	5	6	1
	Asian	3 (3%)	3	0	0
	American Indian	1 (1%)	0	1	0
	Other	1 (1%)	0	0	1
Marital Status***	Married	62 (58%)	48	4	10
	Divorced	16 (15%)	8	2	6
	Never Married	14 (13%)	5	8	1
	Widowed	13 (12%)	10	1	2
	Separated	2 (2%)	2	0	0
Income (n=99)	Less than $9,999	6 (6%)	2	2	2
	$10,000-14,999	4 (4%)	2	1	1
	$15,000-19,999	5 (5%)	4	1	0
	$20,000-29,999	13 (13%)	8	2	3
	$30,000-39,999	11 (11%)	5	3	3
	$40,000-49,999	9 (9%)	3	2	4
	$50,000-59,999	9 (9%)	7	1	1
	$60,000-69,999	5 (5%)	3	1	1
	Over $70,000	37 (37%)	32	2	3

Education	Graduate Degree	13 (12%)	13	0	0
	Bachelors	26 (24%)	18	5	3
	Associate	11 (10%)	7	0	4
	Some college	35 (33%)	24	5	6
	High School Grad	16 (15%)	8	4	4
	9^{th}-12^{th} grade	4 (4%)	1	1	2
	Less than 9^{th}	2 (2%)	2	0	0
Employment	Working Full-Time	26 (24%)	17	5	4
	Working Part-Time	7 (7%)	5	2	0
	Unemployed	3 (3%)	3	0	0
	Homemaker	3 (3%)	3	0	0
	Retired	56 (52%)	39	5	12
	Disabled	10 (9%)	5	2	3
	Other	2 (2%)	1	1	0

**Significant differences between insulin management (p<.01)
***Significant differences between insulin management groups (p<.001)

Health history and diabetes-related complications are reported in Table 14. The majority of subjects were overweight (mean BMI 32.9), on oral medications (72.8% on metformin), with long-standing T2DM (mean 12.6 years) and at least one diabetes-related complication (38% with neuropathy) and co-morbid illness (79% hypertension). Both simple (0.48/week) and severe (0.60/year) hypoglycemia were rare in the overall sample. Some DM complications [foot ulcers (4%), renal failure (3%), and gastroparesis (4%)] were rare in the sample. Type of insulin management strategy was used to compare health and diabetes-related items. Using ANOVA, no significant group differences were found in duration of insulin therapy and amount of severe hypoglycemia. The groups did not differ in the frequency of most DM-related complications and co-morbidities, with the exception of heart disease and chronic pain.

Heart disease was three times greater in subjects taking insulin (26.6% of basal and 26.3% of basal-bolus groups) than oral medications (8.2%; χ=6.411, p<.05). Chronic pain was most likely in subjects using basal-bolus insulin (36.8%), than basal only insulin (6.7%) or oral medications (13.7%; χ=7.057, p<.05). The insulin management groups also differed on type of oral medication used: most subjects on basal-bolus insulin took no oral medications (57.9%; χ=40.481, p<.001), most subjects on basal only insulin took metformin (66.7%; χ=11.443, p<.01), and subjects on oral medications only had a greater frequency of taking two or more oral diabetes medications (45.2%; χ=41.639, p<.001). Subjects using basal-bolus insulin had a longer DM duration [F (2, 100) =6.670, p<.01], more frequent simple hypoglycemia [F (2,104) =4.151, p<.05], and total number of diabetes-related complications [F (2,104) =6.252, p<.01] than subjects on oral medications alone. Per one-way ANOVA, BMI was highest in the basal insulin group [F (2, 102) = 3.876, p<.05]. Erectile dysfunction occurred in the majority of men in the sample (57.7%); this parameter could not be compared across insulin management groups due to insufficient data.

Table 14. Health History of the Sample

Variable		Total Sample N=107 (%)	Oral Medication N= 73	Insulin	
				Basal N=15	Basal-Bolus N=19
BMI*		N=105		N=13	
	Mean ± SD	32.9 ± 6.7	32.5 ± 6.8	37.4 ± 4.4	31.2 ± 6.5
	Range	19.1-53.7	20.3-53.7	31.5-44.6	19.1-45.8
Duration of DM**		N=103		N=12	N=18
	Mean ± SD	12.6 ± 9.2	10.6 ± 7.7	16.5 ± 11	18.0 ± 10.5
	Range	1-39	1-32	3-39	1-38
Oral Medication***	None	14 (13%)	0	3	11
	Metformin	78 (73%)	60	10	8
	Sulfonylurea	40 (37%)	31	6	3
	Sitagliptin	16 (15%)	15	1	0
Insulin Duration (years)		N=30		N=14	N=16
	Mean ± SD	8.3 ± 8.9	n/a	5.0 ± 5.8	11.1 ± 10.2
	Range	1-31		1-18	1-31
Taking byetta?	Yes	9 (8%)	7	2	0
	No	98 (92%)	66	13	19
Simple Hypoglycemia[1]* (episodes/wk.)	Mean ± SD	0.5 ± 1.1	0.3 ± 0.9	0.6 ± 1.1	1.1 ± 1.2
	Range	0-6	0-6	0-3	0-4
Severe Hypoglycemia[1] (episodes/year)	Mean ± SD	0.6 ± 1.9	0.4 ± 1.7	0.5 ± 1.6	1.3 ± 2.5
	Range	0-12	0-12	0-6	0-10
Total # DM Complications *	Mean ± SD	1.4 ± 1.7	1.0 ± 1.3	1.5 ± 1.9	2.5 ± 2.2
	Range	0-7	0-4	0-6	0-7
DM Complications	Neuropathy	38 (36%)	21	6	11
	Claudication	22 (21%)	14	1	7
	PVD	16 (15%)	9	2	5
	Heart Disease*	15 (14%)	6	4	5
	Eye Disease/ Laser Surgery	15 (14%)	8	3	4
Erectile Dysfunction (men only, N=26)		15 (57.7%)	9	1	5
History of Depression?	Yes	36 (34%)	25	6	5
	No	71 (66%)	48	9	14
Co-morbidities	Hypertension	79 (74%)	54	11	14

	Cataracts	41 (38%)	29	4	8
	Arthritis	39 (36%)	27	7	5
	DJD	26 (24%)	18	1	7
	Sleep Apnea	20 (19%)	14	2	4
	Chronic Pain*	18 (17%)	10	1	7
	Asthma	13 (12%)	11	0	2

[1]Hypoglycemia was experienced by a minority of subjects: 79% of subjects reported no hypoglycemic episodes in last week; 83% of subjects reported no severe hypoglycemia in the past year.
*Significant differences between insulin management groups (p<.05)
**Significant differences between insulin management groups (p<.01)
***Significant differences between insulin management groups (p<.001)

Data Analysis per Study Aims

The aims of the study were as follows: (1) to describe the HRQOL of persons with T2DM according to type of glycemic management (Oral meds only, Basal insulin only, Basal-bolus insulin), (2) to determine if HRQOL of persons with T2DM differs depending on type of glycemic management, and (3) to determine if type of glycemic management is predictive of HRQOL after controlling for covariates. Statistical tests performed and assumptions are discussed per aim.

Data Analysis: Aim 1

The first aim of the study was to describe the HRQOL of persons with T2DM according to type of glycemic management. This was done in several steps. First, using the conceptual model for the study, descriptive statistics were generated for measurements on all QOL specific domains (environmental, biologic, symptoms, functional performance, general health perception and quality of life) and are presented in Table 15.

Table 15. Multidimensional Quality of Life Variables per Study Model

Revised Wilson and Cleary HRQOL Concepts	Study Variable	Measurement Tool	Mean (± SD)	Range	Norms	
					Healthy Mean (SD)	Diabetes Mean (SD)
Environmental Characteristics	Access to diabetes care	CIRS item (#15)	91% of subjects reported having insurance that covered most of diabetes costs including medicine			
	Social Support	CIRS Overall	2.85 (± 0.55)	1.6 – 4.5		2.7 (0.5)
		CIRS Health Care Team	3.97 (± 0.91)	1.3 – 5.0		3.4 (1.1)
		CIRS Family/Friends	2.30 (± 0.95)	1.0 – 4.7		2.4 (1.0)
		CIRS Personal	3.23 (± 0.94)	1.0 – 5.0		3.3 (0.8)
		CIRS Work (n=35)	2.78 (± 1.13)	1.0 – 5.0		2.5 (0.9)
		CIRS Neighborhood	2.32 (± 0.76)	1.0 – 4.8		2.2 (0.9)
		CIRS Media/Policy	3.46 (± 0.76)	1.7 – 5.0		3.4 (0.8)
		CIRS Organizations	2.03 (± 0.93)	1.0 – 4.7		1.9 (0.9)
Biological function	Glycemic control	A1C	7.990 (±1.579)	5.4 – 13.1	4.0 - 5.6	
Symptoms	Mood	WBQ-12: General Well-Being	24.12 (± 6.67)	5 – 36		24.4 (7.2)
		Energy	6.60 (± 2.70)	0-12		7.5 (3.0)
		Positive Well Being	7.46 (± 2.97)	0-12		7.6 (2.8)
		Negative Well-Being	1.90 (± 2.23)	1-12		2.7 (2.9)
	DM-related (Total)	DSC-R overall	1.11 (± 0.77)	0 - 3.91		0.82 (0.71)
	Hypoglycemia	DSC-R: hypoglycemia	1.21 (± 1.18)	0 – 4.33		0.80 (1.00)

	Hyperglycemia	DSC-R: hyperglycemia	1.44 (± 1.07)	0 – 4.25		1.24 (1.15)
	Pain	DSC-R: neurosensory subscale	0.91 (± 1.03)	0 – 4.33		0.60 (0.82)
	Vision	DSC-R: ophthalmologic	0.67 (± 0.93)	0 – 4.6		0.61 (0.87)
	Activity tolerance	DSC-R: cardiac	0.89 (± 0.84)	0 – 3.5		0.67 (0.79)
Functional Performance	Social functioning	SF-12 (v2) Mental Composite Score	50.93 (± 9.91)	23.56 – 70.71	50 (10)	47.28 (10.72)
	Role functioning	SF-12 (v2) Physical Composite Score	41.47 (± 11.97)	12.18 – 60.42	50 (10)	41.52 (11.07)
	Diabetes Self-Management	Self-Care Inventory-Revised	61.61 (± 13.68)	28.85 – 89.29		64.4 (17.9)
General health perception	Overall health	General health item of SF-12 (v2)	3.06 (± 0.95)	1 – 5		
	Acceptance of diabetes	Appraisal of Diabetes Scale	17.10 (± 4.46)	9 - 28		18.65 (4.04)
Quality of life	Perceived HRQOL	Quality of Life Index Overall	21.81 (± 4.70)	8.15 - 29.45	23.00	20.56
		QLI: Health & Functioning	20.71 (± 5.14)	5 – 30		
		QLI: Social & Economic	22.45 (± 5.11)	10.29 – 30		
		QLI: Psych & Spiritual	22.81 (± 5.71)	2.57 – 30		
		QLI: Family	22.60 (± 5.56)	6.25 – 30		

Note. HRQOL = Health-Related Quality of Life; CIRS = Chronic Illness Resources Survey; A1C = Glycosylated Hemoglobin; WBQ-12= Well-Being Questionnaire 12; DSC-R = Diabetes Symptom Checklist-Revised.

Sources for Norms: CIRS: Glasgow, Strycker, Toobert & Eakin, 2000; A1C: National Diabetes Information Clearinghouse, 2011; WBQ-12: Pouwer et al., 1999; DSC-R: Arbuckle et al., 2009; SF-12(v2): Ware, Kosinski, Turner-Bowker & Gandek, 2002; SCI-R: Weinger, Butler, Welch & LaGreca, 2005; ADS: Carey et al., 1991; QLI: Ferrans & Powers (n.d.b)

Second, relationships between key study variables were examined using Pearson's correlations and are presented in Table 16. Quality of life was found to be positively correlated with age ($r=.25$, $p<.05$), social support ($r=.31$, $p<.01$), general well-being ($r=.65$, $p<.01$), role functioning (SF-12 PCS, $r=.43$, $p<.01$), and social functioning (SF-12 MCS, $r=.50$, $p<.01$). In contrast, QOL was found to be negatively correlated with BMI ($r=-.29$, $p<.01$), A1C ($r=-.21$, $p<.05$), DM complications ($r=-.24$, $p<.05$), DM symptoms ($r=-.54$, $p<.01$), and ADS scores ($r=-.50$, $p<.01$). This means that QOL decreased as obesity, poor glycemic control, and diabetes-related complications and symptoms increased. Quality of life was also decreased in subjects who had poor acceptance of their disease as measured by the ADS. Insulin management and diabetes self-care were not significantly correlated with QOL. As many of the variables are significantly correlated, it should be noted that no correlation is greater than .65, which is important as correlations greater than .90 indicate collinearity (Field, 2009).

Third, because gender is a major variable impacting QOL perceptions, the sample was examined for gender differences in QOL and related study variables (Table 17). Women and men did not significantly differ on several factors: ethnicity, duration of DM, social support, glycemic control (A1C), BMI, diabetes self-care, and acceptance of diabetes (ADS). In addition, there were insufficient numbers per group to analyze insulin management by gender. Details of gender differences are provided in Table 17. Men in the sample were older ($t= 2.078$, $p<.05$) and more likely to be married ($\chi=16.918$, $p<.01$). Women in the study reported higher incidences of non-partnered marital status

(divorced, never married, or widowed; Table 17). Although not statistically significant, there were more minority women than men in the sample (19.8% vs. 3.8%, χ=5.219, n.s.). Diagnosed depression was more common in women than men (39.5% vs. 15.4%, χ=5.130, $p<.05$). Diabetes-related complications were more prevalent in men ($t=2.634$, $p<.05$); however, both genders reported equivalent amounts of diabetes related symptoms, with exception of cardiac/activity symptoms, which occurred more frequently in women ($t= -2.765$, $p<.01$).

Table 16. Correlations between Key Variables

	CIRS	Insulin Mgmt.	BMI	A1C	DM Complications	General Well-Being	DSC Total	SF Physical	SF Mental	Self-Care	Appraisal of Diabetes	QLI overall
Age	-.119	-.123	-.146	-.169	.019	**.208***	-.181	-.060	**.281****	.122	**-.293****	**.246***
CIRS		-.171	-.132	-.003	-.137	**.202***	-.110	**.195***	.063	**.302****	-.121	**.311****
Insulin Management			-.009	**.368****	**.323****	-.134	.055	**-.257****	-.002	**.336****	**.212***	-.185
BMI				.157	.078	**-.223***	.072	**-.340****	-.131	**-.286****	.080	**-.286****
A1C					-.007	-.173	.130	**-.211***	-.096	.046	**.292****	**-.207***
DM Complications						-.123	**.335****	**-.421****	.113	.095	**.331****	**-.242***
General Well-Being							**-.634****	**.442****	**.738****	.122	**-.480****	**.646****
Diabetes Symptoms								**-.537****	**-.395****	-.124	**.611****	**-.543****
SF-12 PCS									-.014	.036	**-.394****	**.430****
SF-12 MCS										.145	**-.259****	**.502****
Self-Care											-.087	.148
ADS												**-.504****

**Correlation is significant at the p<.01 level (2-tailed), *Correlation is significant at the p<.05 level (2-tailed)

Table 17. Study Variables Differing by Gender

Study Variable	Measurement Tool	Total Sample Mean (± SD)	Men (n=26) Mean (SD)	Women (n=81) Mean (SD)
Age*		63.8 (11.8)	67.9 (9.32)	62.4 (12.24)
Marital Status**			92.3% married	46.9% married 18.5% divorced 17.3% single 14.8% widowed
Diagnosed with Depression*			15.4%	39.5%
Insulin Management --Oral --Basal Insulin --Basal-Bolus			 18 1 7	 55 14 12
DM Complications*		1.35 (1.67)	2.08 (1.81)	1.11 (1.57)
Mood: WBQ-12	General Well-Being**	24.12 (6.67)	27.50 (6.54)	23.03 (6.38)
	Energy*	6.60 (2.70)	7.62 (2.74)	6.28 (2.62)
	Positive Well Being**	7.46 (2.97)	8.88 (2.72)	7.00 (2.91)
	Negative Well-Being*	1.90 (2.23)	1.00 (2.10)	2.19 (2.21)
Diabetes Symptoms	DSC-R overall (n.s.)	1.11 (0.77)	0.94 (0.79)	1.16 (0.76)
	DSC-R: cardiac**	0.89 (0.84)	0.58 (0.56)	0.99 (0.89)
Social functioning	SF-12 (v2) Mental Composite Score*	50.93 (9.91)	54.91 (9.03)	49.64 (9.89)
Perceived HRQOL	QLI Overall**	21.81 (4.70)	23.98 (4.13)	21.12 (4.69)
	QLI: Health & Functioning*	20.71 (5.14)	22.77 (4.90)	20.05 (5.06)
	QLI: Social & Economic**	22.45 (5.11)	24.72 (3.11)	21.72 (5.42)
	QLI: Psych & Spiritual**	22.81 (5.71)	25.06 (4.27)	22.09 (5.94)
	QLI: Family*	22.60 (5.56)	24.92 (5.24)	21.86 (5.49)

* p<.05, **p<.01

The WBQ-12 measured both positive and negative mood in the study. Men reported higher general well-being (t=3.089, p<.01), positive well-being (t=2.917, p<.01), and energy (t=2.241, p<.05) than women in the study. Women reported greater negative well-being (t=-2.425, p<.05). Men also reported higher levels of mental performance (mental composite summary) on the SF-12 than women (t=2.389, p<.05). The SF-12 did not detect significant physical composite score differences between genders.

Quality of life was also reported as lower by women. Women reported lower overall quality of life (21.12 vs. 23.98, t=2.784, p<.01) than men. Quality of life per all QLI subscales was also reported as significantly lower in women (Table 18). The effect of gender on QOL was tested as a moderating variable with general well-being; however, this regression was not significant. Nevertheless, gender remains an important factor in understanding QOL in T2DM.

Table 18. Quality of Life by Gender

	Levene's Test for Equality of Variances		Equal variances assumed	t-test for Equality of Means		
	F	Sig.		t	df	Sig. (2-tailed)
QLI overall	.434	.511	Yes	2.784	105	.006
Health & Functioning	.030	.864	Yes	2.397	105	.018
Social & Economic	13.558	.000	No	3.491	75.087	.001
Psychological & Spiritual	3.192	.077	Yes	2.359	105	.020
Family	.151	.698	Yes	2.499	104	.014

Finally, type of management among the groups based on medication dosing frequency [Oral meds only, Basal Insulin (once or twice daily), Basal-Bolus Insulin (three or more times daily)] was examined. Descriptive statistics for QOL and the subscales of QOL are presented below (Table 19).

Table 19. Quality of Life by Type of Glycemic Management

Quality of Life Index	Total Sample N=107	Oral Medication N=73	Insulin Basal N=15	Insulin Basal-Bolus N=19
Overall	21.81 (± 4.70)	22.40 (±4.42)	20.91 (±4.34)	20.27 (±5.74)
Health & Functioning	20.71 (± 5.14)	21.31 (±4.93)	19.89 (±4.56)	19.07 (±6.09)
Social & Economic	22.45 (± 5.11)	23.38 (±4.82)	20.61 (±5.16)	20.35 (±5.43)
Psych & Spiritual	22.81 (± 5.71)	23.43 (±5.10)	22.44 (±5.72)	20.73 (±7.49)
Family	22.60 (± 5.56)	22.71 (±5.49)	21.77 (±6.04)	22.87 (±5.71)

Data Analysis: Aim 2

To determine if HRQOL of persons with T2DM differs depending on type of glycemic management, subjects were divided into three groups based on the type of glycemic management: oral meds only, insulin once or twice daily (basal), insulin three or more times daily (basal-bolus). The dependent variable, quality of life, was represented by QLI scores. Group differences in QLI scores were examined using Analysis of Variance (ANOVA), with post-hoc testing to establish pair-wise group differences (Munro, 2005).

Group means of the total and subscale QOL were compared using one-way ANOVA. ANOVA assumptions include homogeneity of variance, independent observations, and normality; these are discussed in Appendix H. There was no violation

of homogeneity of variance in QLI among the three groups per Levene's test. Remaining assumptions of ANOVA were met. The analysis revealed that participants' overall quality of life was not significantly different across the three groups [Table 20; F (2, 104) = 1.89, p>.05].

A post-hoc power analysis was conducted to verify the power achieved by the one-way ANOVA of QOL by insulin management in this sample (n=107). Per post-hoc analysis, the power obtained was 38 percent. To achieve 80% power in the one-way ANOVA, a sample size of 285 participants was required. Due to lack of significant findings, which may be due to low study power, the second study aim was not supported. That is, no significant group differences in QOL were detected based on insulin management.

Table 20. Examining Quality of Life by Insulin Management (ANOVA)

		Sum of Squares	df	Mean Square	F	Sig.
QLI overall	Between Groups	82.354	2	41.177	1.892	.156
	Within Groups	2263.090	104	21.760		
	Total	2345.445	106			

To examine complex interactions that may confound QOL measurement in this population, Multifactorial Analysis of Variance (MANOVA) was used (Table 21). In the MANOVA, the variables tested included: type of glycemic management (oral, basal insulin, or basal-bolus insulin), glycemic control (Hemoglobin A1C), diabetes symptoms, mood (psychological well-being), diabetes self-care, acceptance of diabetes, and quality

of life. These variables were chosen according to the study model, which represents subjects' overall adjustment to life with diabetes. Sources of variation in the MANOVA included main effects as well as interactions between variables.

Table 21. Study Model and MANOVA Variables

Revised Wilson and Cleary HRQOL Concepts	Study Variable	Measurement Tool
Biological function	Insulin dosing frequency	Oral Medication Basal Insulin Basal-bolus Insulin
	Glycemic Control	A1C
Symptoms	Mood	WBQ-12: General Well-Being (overall)
	Diabetes-related Symptoms	DSC-R overall
Functional Performance	Diabetes Self-Management	Self-Care Inventory-Revised
General health perception	Acceptance of diabetes	Appraisal of Diabetes Scale
Quality of life	Perceived HRQOL	Quality of Life Index Overall

Assumptions of MANOVA include independence, random sampling, multivariate normality, and homogeneity of covariance matrices (Appendix H). Wilks' Lambda ($p = .001$, $p<.01$) indicated that the set of six dependent variables significantly differed for the independent variable (insulin management). To determine what variables the groups differed on, the between-group effects were examined (Table 22). Glycemic control [A1C; $F(2, 95) = 7.044$; $p=.001$] and diabetes self-care [$F(2, 95) = 4.620$, $p<.05$) significantly differed for the insulin management groups. Post-hoc testing revealed that A1C was significantly higher in subjects on basal insulin ($p<.05$) and basal-bolus insulin ($p<.05$) than subjects on oral medication (Table 23). Also, subjects using basal-bolus

insulin management performed considerably more diabetes self-care than patients on oral medications ($p<0.05$). Per MANOVA, the remaining dependent variables (general well-being, diabetes symptoms, and acceptance of diabetes) and QOL were not found to differ significantly between insulin management groups.

Table 22. Tests of Between-Subjects Effects (MANOVA)

Source	Dependent Variable	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	Hemoglobin A1C	28.674[a]	2	14.337	7.044	.001
	QLI	77.891[b]	2	38.946	1.840	.165
	DSC Total	.257[c]	2	.129	.237	.789
	Self-Care Score	1559.868[d]	2	779.934	4.620	.012
	General Well-Being	46.107[e]	2	23.054	.533	.588
	ADS total score	69.921[f]	2	34.961	1.818	.168
Intercept	Hemoglobin A1C	4189.057	1	4189.057	2058.065	.000
	QLI	27068.731	1	27068.731	1278.967	.000
	DSC Total	75.319	1	75.319	139.011	.000
	Self-Care Score	243848.681	1	243848.681	1444.525	.000
	General Well-Being	34395.081	1	34395.081	795.935	.000
	ADS total score	17875.180	1	17875.180	929.324	.000
Insulin	**Hemoglobin A1C**	28.674	2	14.337	7.044	**.001**
	QLI	77.891	2	38.946	1.840	.165
	DSC Total	.257	2	.129	.237	.789
	Self-Care Score	1559.868	2	779.934	4.620	**.012**
	General Well-Being	46.107	2	23.054	.533	.588
	ADS total score	69.921	2	34.961	1.818	.168
Error	Hemoglobin A1C	189.295	93	2.035		
	QLI	1968.301	93	21.165		
	DSC Total	50.390	93	.542		
	Self-Care Score	15699.226	93	168.809		
	General Well-Being	4018.851	93	43.213		
	ADS total score	1788.818	93	19.235		
Total	Hemoglobin A1C	6225.140	96			
	QLI	47644.991	96			
	DSC Total	164.592	96			

	Self-Care Score	374737.464	96			
	General Well-Being	61200.000	96			
	ADS total score	29433.000	96			
Corrected Total	Hemoglobin A1C	217.970	95			
	QLI	2046.193	95			
	DSC Total	50.647	95			
	Self-Care Score	17259.093	95			
	General Well-Being	4064.958	95			
	ADS total score	1858.740	95			

a. R Squared = .132 (Adjusted R Squared = .113)
b. R Squared = .038 (Adjusted R Squared = .017)
c. R Squared = .005 (Adjusted R Squared = -.016)
d. R Squared = .090 (Adjusted R Squared = .071)
e. R Squared = .011 (Adjusted R Squared = -.010)
f. R Squared = .038 (Adjusted R Squared = .017)

Table 23. Post Hoc Tests (MANOVA)

Dependent Variable	(I) Taking insulin	(J) Taking insulin	Mean Diff. (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Hgb A1C	No	Yes, Basal	-1.312*	.420	.010	-2.356	-.267
		Yes, Basal-Bolus	-1.042*	.398	.036	-2.031	-.053
	Yes, Basal	No	1.312*	.420	.010	.267	2.356
		Yes, Basal-Bolus	.270	.522	.875	-1.029	1.569
	Yes, Basal-Bolus	No	1.042*	.398	.036	.053	2.031
		Yes, Basal	-.270	.522	.875	-1.569	1.029
QLI overall	No	Yes, Basal	1.215	1.354	.670	-2.153	4.582
		Yes, Basal-Bolus	2.349	1.282	.192	-.840	5.538
	Yes, Basal	No	-1.215	1.354	.670	-4.582	2.153
		Yes, Basal-Bolus	1.134	1.684	.797	-3.054	5.322
	Yes, Basal-Bolus	No	-2.349	1.282	.192	-5.538	.840
		Yes, Basal	-1.134	1.684	.797	-5.322	3.054
DSC Total	No	Yes, Basal	-.021	.217	.995	-.560	.518
		Yes, Basal-Bolus	-.141	.205	.789	-.652	.369
	Yes, Basal	No	.021	.217	.995	-.518	.560
		Yes, Basal-Bolus	-.120	.269	.906	-.790	.550

	Yes, Basal-Bolus	No	.141	.205	.789	-.369	.652
		Yes, Basal	.120	.269	.906	-.550	.790
Self-Care Score	No	Yes, Basal	-3.834	3.823	.606	-13.345	5.6766
		Yes, Basal-Bolus	-10.88*	3.621	.013	-19.888	-1.875
	Yes, Basal	No	3.834	3.823	.606	-5.677	13.345
		Yes, Basal-Bolus	-7.048	4.755	.338	-18.876	4.781
	Yes, Basal-Bolus	No	10.882*	3.621	.013	1.875	19.888
		Yes, Basal	7.048	4.755	.338	-4.781	18.876
General Well-Being	No	Yes, Basal	1.78	1.934	.657	-3.03	6.59
		Yes, Basal-Bolus	1.16	1.832	.818	-3.40	5.72
	Yes, Basal	No	-1.78	1.934	.657	-6.59	3.03
		Yes, Basal-Bolus	-.62	2.406	.968	-6.60	5.37
	Yes, Basal-Bolus	No	-1.16	1.832	.818	-5.72	3.40
		Yes, Basal	.62	2.406	.968	-5.37	6.60
ADS total score	No	Yes, Basal	.52	1.290	.921	-2.69	3.73
		Yes, Basal-Bolus	-2.15	1.222	.219	-5.19	.89
	Yes, Basal	No	-.52	1.290	.921	-3.73	2.69
		Yes, Basal-Bolus	-2.67	1.605	.256	-6.66	1.32
	Yes, Basal-Bolus	No	2.15	1.222	.219	-.89	5.19
		Yes, Basal	2.67	1.605	.256	-1.32	6.66

Scheffe test of multiple comparisons based on observed means.

The error term is Mean Square (Error) = 19.235.

*The mean difference is significant at the .05 level.

Data Analysis: Aim 3

The third aim of the study was to determine if type of glycemic management is predictive of HRQOL after controlling for covariates. This aim was met through multiple regression analysis. Assumptions of multiple regression include variable types, non-zero variance, multicollinearity, non-externally correlated predictors, homoscedasticity, independent error terms, normally distributed errors, independence, and linearity. The assumptions of multiple regression were met (Appendix H).

First, multiple regression was used to examine the effect of five predictors on QOL. The simultaneous method, or forced entry, was used to enter glycemic control (A1C), general well-being, diabetes symptoms, diabetes self-management (SCI-R), and appraisal of diabetes as predictors of QOL. The results indicated that the five predictors accounted for 49% of the variance [R^2 = .49, F (5, 90) = 17.04, p< .001] (Table 24). Of these predictors, examination of beta weights showed that only general well-being (β = .51, p<.001) and appraisal of diabetes (β = -.23, p<.05) significantly contributed to prediction of QOL (Table 25).

Table 24. Regression Analysis

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.697[a]	.486	.458	3.41745	.486	17.041	5	90	.000	2.160

a. Predictors: (Constant), ADS, Self-Care Score, A1C, General Well-Being, Diabetes Symptoms

b. Dependent Variable: QLI overall

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	995.087	5	199.017	17.041	.000[b]
	Residual	1051.106	90	11.679		
	Total	2046.193	95			

a. Dependent Variable: QLI overall

b. Predictors: (Constant), ADS, Self-Care Score, A1C, General Well-Being, Diabetes Symptoms

Table 25. Regression Coefficients

Coefficients[a]

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
(Constant)	17.020	3.474		4.899	.000	10.118	23.921					
Hemoglobin A1C	-.115	.241	-.037	-.476	.636	-.594	.365	-.198	-.050	-.036	.920	1.087
DSC Total	-.247	.682	-.039	-.362	.718	-1.601	1.108	-.502	-.038	-.027	.496	2.016
Self-Care Score	.020	.027	.059	.771	.443	-.032	.073	.182	.081	.058	.963	1.039
General Well-Being	.362	.068	.510	5.282	**.000**	.226	.498	.653	.486	.399	.613	1.632
Appraisal of DM	-.243	.102	-.232	-2.386	**.019**	-.446	-.041	-.499	-.244	-.180	.605	1.632

a. Dependent Variable: QLI overall

An additional multiple regression analysis was performed to examine a moderated model of diabetes self-care, general well-being, and QOL (Figure 3). General well-being had a main effect on QOL, but diabetes self-care did not have a significant main effect on QOL. However, an interaction term between general well-being and diabetes self-care showed a significant predictive effect on QOL ($\beta = -.155$, $p<.05$). The model of general well-being moderated by diabetes self-care to predict QOL was significant [$R^2 = .45$, $F (3, 102) = 27.73$, $p<.001$]. Model summary is provided in Table 26.

Figure 3. Moderation Model

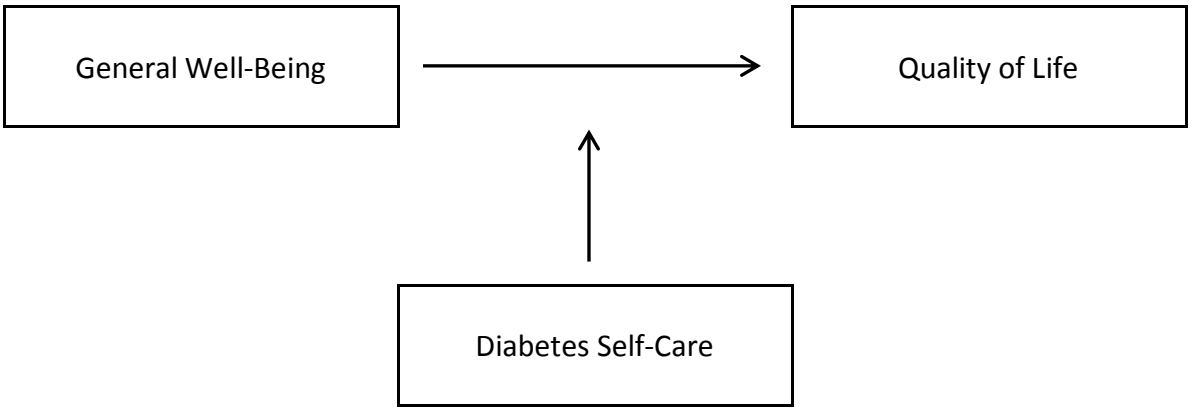


Table 26. Moderated Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.646[a]	.418	.412	3.61046	.418	74.569	1	104	.000
2	.653[b]	.426	.415	3.60215	.008	1.480	1	103	.227
3	.670[c]	.449	.433	3.54545	.023	4.321	1	102	.040

1. Predictors: (Constant), General Well-Being
2. Predictors: (Constant), General Well-Being, Diabetes Self-Care
3. Predictors: (Constant), General Well-Being, Diabetes Self-Care, Interaction (GWB x SCI)

To further understand the moderation effects of diabetes self-care on QOL, the model was analyzed with high and low levels of self-care. Multiple regressions using high and low self-care were performed with the moderated model (Table 27). Using the coefficients from these regressions, equations representing QOL moderated by self-care were developed using one standard deviation of general well-being. General well-being significantly increased participants' quality of life when self-care scores were lower. Diabetes self-care moderates the relationship between general well-being and QOL. General well-being was more likely to increase participants' quality of life when they reported lower self-care scores, compared to the participants whose self-care scores were higher. The moderation effect of self-care is shown graphically in Figure 4.

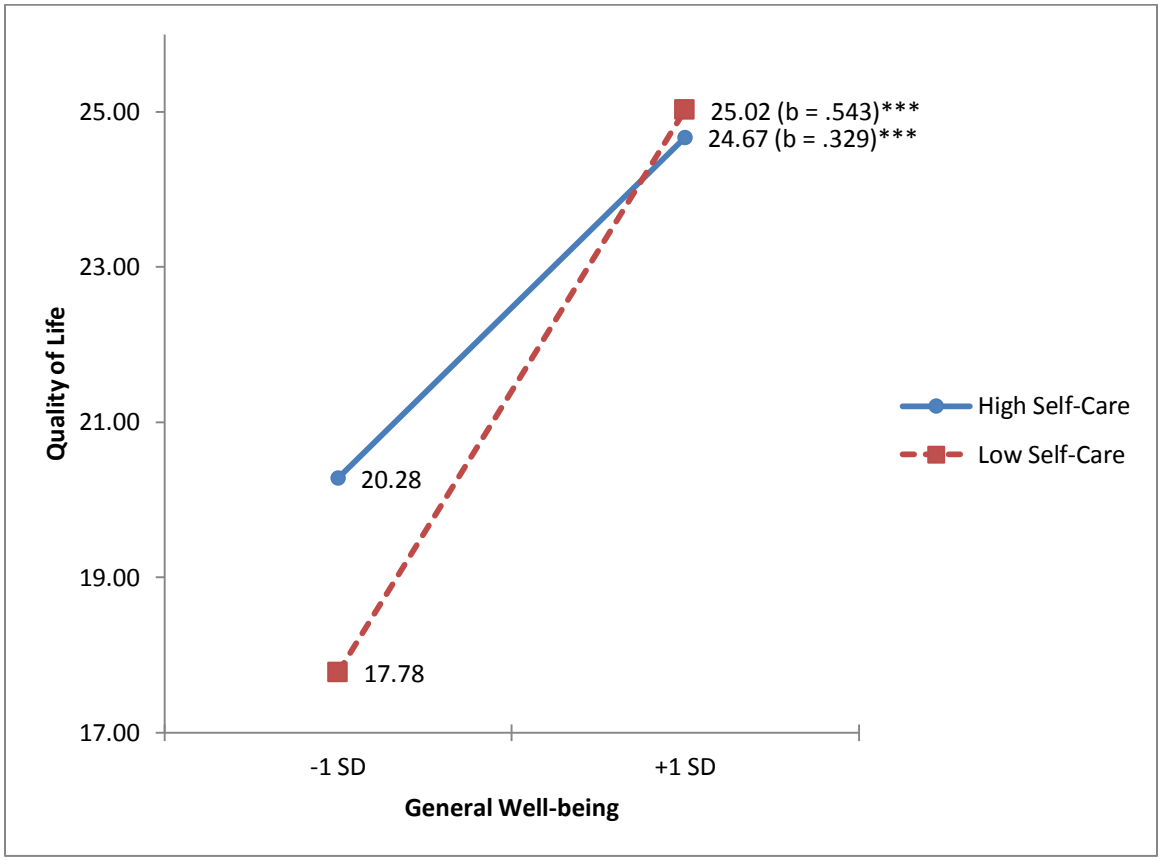
Table 27. Moderated Model of Quality of Life by High and Low Self-Care

Coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	22.474	.499		45.068	.000	21.485	23.463
General Well-Being	.329	.078	.466	4.238	.000	.175	.483
High Self-Care	.040	.026	.114	1.524	.131	-.012	.092
Interaction: High SC x GWB	-.008	.004	-.227	-2.079	.040	-.015	.000
(Constant)	21.400	.490		43.663	.000	20.428	22.372
General Well-Being	.543	.069	.769	7.835	.000	.405	.680
Low Self-Care	.040	.026	.114	1.524	.131	-.012	.092
Interaction: Low SC x GWB	-.008	.004	-.206	-2.079	.040	-.015	.000

Dependent variable: QLI overall

Figure 4. Quality of Life Moderated by Self-Care



Given the gender differences noted in mood and QOL, an exploratory analysis was conducted to further analyze the moderated model of general well-being, self-care and QOL. The statistical analyses were repeated separately by gender (Tables 28 & 29). The results differed significantly by gender. In men, the moderated model was not supported. Only general well-being had a significant main effect on QOL. Self-care and the interaction had no significant effects. In women, the moderated model approached statistical significance [R2 = .39, F (3, 76) = 15.88, p=0.066]. General well-being had a significant main effect. Self-care did not. The interaction between self-care and general

well-being was a near-significant predictor of QOL in women (p=0.066). As the study had low power, these findings indicate that self-care has a potential to moderate general well-being on QOL in women. The moderated model, split by gender, is shown in Figure 5.

Table 28. Moderated Model Summary (by Gender)

Males

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.749[b]	.562	.543	2.79206	.562	30.746	1	24	.000
2	.752[c]	.565	.527	2.84170	.003	.169	1	23	.685
3	.752[d]	.566	.506	2.90285	.001	.041	1	22	.841

a. Gender = Male

b. Predictors: (Constant), General Well-Being

c. Predictors: (Constant), General Well-Being, Diabetes Self-Care

d. Predictors: (Constant), General Well-Being, Diabetes Self-Care, Interaction (GWB x SCI)

Females

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.582[b]	.339	.330	3.84644	.339	39.950	1	78	.000
2	.598[c]	.357	.340	3.81730	.018	2.196	1	77	.142
3	.621[d]	.385	.361	3.75704	.028	3.490	1	76	.066

a. Gender = Female

b. Predictors: (Constant), General Well-Being

c. Predictors: (Constant), General Well-Being, Diabetes Self-Care

d. Predictors: (Constant), General Well-Being, Diabetes Self-Care, Interaction (GWB x SCI)

Table 29. Moderated Model of Quality of Life by High and Low Self-Care (by Gender)

Coefficients: Males

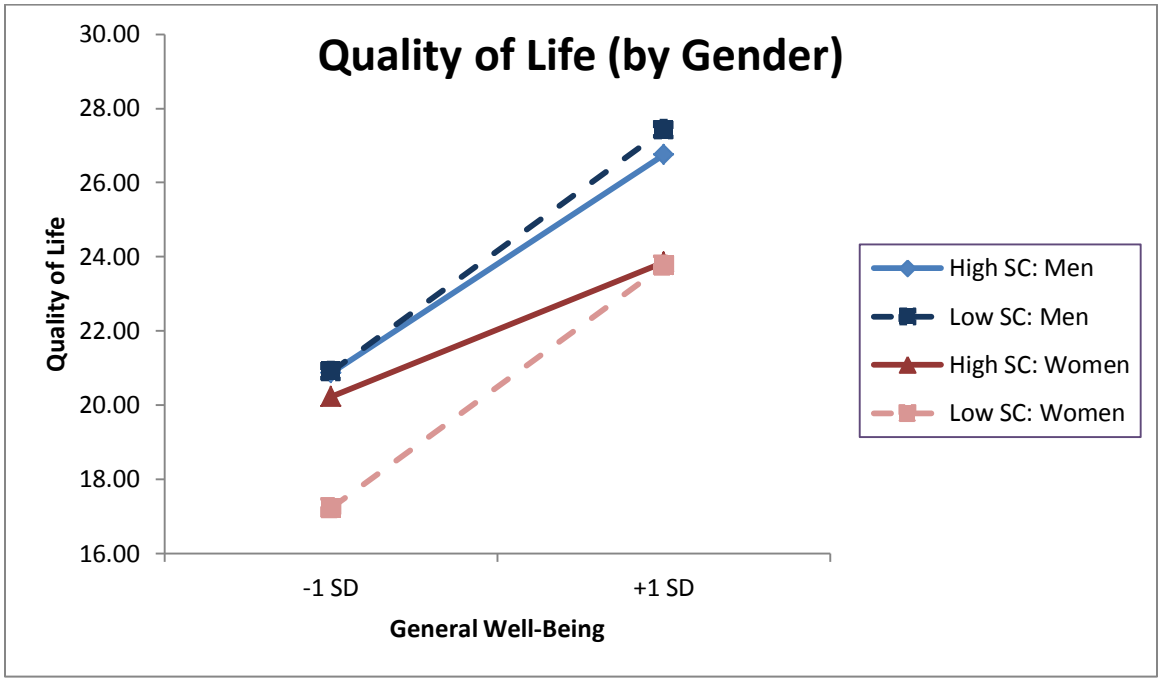
Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	23.805	.868		27.417	.000	22.005	25.606
General Well-Being	.451	.148	.714	3.051	.006	.145	.758
High Self-Care	-.014	.048	-.043	-.281	.782	-.114	.087
Interaction: High SC x GWB	-.002	.009	-.049	-.203	.841	-.020	.017
(Constant)	24.165	.846		28.574	.000	22.411	25.918
General Well-Being	.499	.146	.789	3.417	.002	.196	.802
Low Self-Care	-.014	.048	-.043	-.281	.782	-.114	.087
Interaction: Low SC x GWB	-.002	.009	-.049	-.203	.841	-.020	.017

Coefficients: Females

Model	Unstandardized Coefficients		Standardized Coefficients	T	Sig.	95.0% Confidence Interval for B	
	B	Std. Error	Beta			Lower Bound	Upper Bound
(Constant)	21.993	.607		36.223	.000	20.784	23.202
General Well-Being	.278	.100	.377	2.790	.007	.079	.476
High Self-Care	.054	.031	.155	1.700	.093	-.009	.116
Interaction: High SC x GWB	-.009	.005	-.250	-1.868	.066	-.018	.001
(Constant)	20.534	.599		34.296	.000	19.342	21.727

General Well-Being	.520	.087	.706	5.958	.000	.346	.694
Low Self-Care	.054	.031	.155	1.700	.093	-.009	.116
Interaction: Low SC x GWB	-.009	.005	-.223	-1.868	.066	-.018	.001

Figure 5. Quality of Life and General Well-Being Moderated by Self-Care (by Gender)



CHAPTER FIVE

DISCUSSION

This dissertation study was conducted to examine quality of life in patients with type 2 diabetes according to type of glycemic management. The aims of the dissertation study were: (1) to describe the HRQOL of persons with T2DM according to type of glycemic management [Oral meds only, Basal insulin only (once or twice daily), Basal-bolus insulin (three or more times daily)], (2) to determine if HRQOL of persons with T2DM differs depending on type of glycemic management, and (3) to determine if type of glycemic management is predictive of HRQOL after controlling for covariates. Based on a review of the literature, it was hypothesized that persons with T2DM on basal-bolus insulin would report higher quality of life when covariates were controlled. Intensive diabetes management is recommended to minimize diabetes-related complications and maximize longevity. However, the QOL effects of intensive diabetes management have not been extensively explored, especially in T2DM.

The vast majority of prior research has examined quality of life in persons with T1DM (Table 1; Appendix A). Subjects with T2DM have been included in a minority of trials, although this has been recently changing (Table 1; Appendix A). Also, existing studies have not conceptualized quality of life as a multidimensional construct.

This dissertation study attempted to understand quality of life in T2DM by using the Revised Wilson and Cleary Model of Quality of Life (Ferrans, Zerwic, Wilbur & Larson, 2005). This model quantifies QOL by recognizing both individual and environmental influences. Five dimensions (biological function, symptoms, functional status, general health perceptions, and overall quality of life) are identified in the model as constructs depicting QOL.

Characteristics of Overall Sample

The majority of the sample was female (75.7%), non-Hispanic (96.2%), Caucasian (84.1%), married (57.9%), retired (52.3%), and an average age of 64 years. Although T2DM occurs in all ages and racial groups, it is more prevalent in older adults (≥65 years of age), men, and racial/ethnic minorities (CDC, 2014). Diabetes more frequently occurs in Native Americans/Alaskan Natives (15.9%), Non-Hispanic blacks (13.2%), and Hispanics (12.8%) than in non-Hispanic whites (7.6%; CDC, 2014). The dissertation study's homogenous sample represents only one subset of the population of persons with diabetes. Despite the small sample size and composition, differences were noted between groups based on type of insulin management. The insulin management groups did not differ in key areas (gender, ethnicity, income, education, and employment). However, differences were found between groups in race and marital status. Subjects using basal-bolus insulin, or intensive insulin management, were more likely to be Caucasian. Black subjects were most likely to be on basal insulin only. Subjects taking basal insulin only were most likely to be single (never married).

In health history and diabetes-related complications, the majority of subjects were similar to the overall population of persons with T2DM (CDC, 2014; Davies, Brophy, Williams & Taylor, 2006; The Action to Control Cardiovascular Risk in Diabetes Study Group, 2008; Shah et al., 2011). The dissertation study subjects were overweight (mean BMI 32.9), on oral medications (72.8% on metformin), with long-standing T2DM (mean 12.6 years) and had at least one diabetes-related complication (38% with neuropathy) and co-morbid illness (79% hypertension). As expected, hypoglycemia was rare in the overall sample. Comparing subjects based on insulin management strategy revealed no differences in the frequency of most DM-related complications and co-morbidities, with the exception of heart disease and chronic pain. Subjects taking insulin had more heart disease than those taking oral medications only; however, this may be due to the significantly longer duration of DM among subjects taking insulin. Subjects using basal-bolus insulin were most likely to report chronic pain, despite equivalent (or lower) rates of obesity, neuropathy, and joint disease. The etiology of this finding is unclear, but the impact of chronic pain on QOL cannot be discounted. Basal-bolus subjects also had more frequent simple hypoglycemia and total number of diabetes-related complications than subjects on oral medications alone. The majority of male subjects reported erectile dysfunction, which can decrease QOL (McCabe & Althof, 2013). Due to insufficient data, this parameter could not be compared across insulin management groups.

Discussion of Aim 1: Describing QOL

The first aim was to describe the HRQOL of persons with T2DM according to type of glycemic management. This was done in three ways: reporting QOL domains from the dissertation study's conceptual model, examining correlations between key study constructs, and comparing QOL based on gender differences. The conceptual model for the dissertation study was used to describe participants' QOL by specific domains (environmental, biologic, symptoms, functional performance, general health perception and quality of life).

Environmental

Subjects reported high levels of access to diabetes care and social support. The vast majority of subjects (91%) reported coverage of most of their diabetes costs, including medicine. This is significantly higher than the percentage of adults with health insurance in the last US census (81% having private and/or government health insurance; DeNavas-Walt, Proctor & Smith, 2010). The dissertation study subjects reported high levels of social support. Overall social support was reported at higher levels (*M*=2.85) than in other studies using the CIRS (*M*=2.7; Glasgow, Strycker, Toobert & Eakin, 2000; Glasgow, Toobert, Barrera & Strycker, 2004). Prior studies using the CIRS are limited by size and lack of racial/ethnic diversity (>90% Caucasian). In a study of adults with chronic illness including DM (n=123), support provided by the health care team was reported as lower (*M*=3.4) than the dissertation study's findings (*M*=3.97; Glasgow et al., 2000). Another study of older adult females with T2DM (n=293)

reported lower social support than the dissertation study participants, specifically in health care team (*M*=3.64), personal (*M*=3.06), neighborhood (*M*=2.14), and organizational (*M*=1.71; Glasgow et al., 2004) dimensions. In a systematic review of the literature, Strom and Egede found that the vast majority of studies provided strong evidence for the relationship between social support and improved DM outcomes (2012). Greater social support was linked to improved clinical outcomes (glycemic control, less DM-symptoms) in 34 of 37 research studies and to improved self-care and/or DSM in 12 of 13 studies (Strom & Egede, 2012). Social support is an important dimension of QOL. In access to care and social support, the dissertation study subjects had average or above average environmental function.

Biological Function

Participants had a mean A1C of 7.9, with a wide range (5.4-13). Similar to national averages, the majority of the dissertation study subjects had inadequate glycemic control. In 2010, per National Health and Nutrition Examination Survey data, only 52.5% of U.S. adults with diabetes achieved the treatment goal of A1C less than 7% (Casagrande et al., 2013). In this study, 27% of subjects met the treatment goal of A1C less than 7%. Suboptimal control (A1C between 7-8%) was achieved by an additional 33% of the dissertation study sample. This study's suboptimal glycemic control may be due to the revised glycemic control recommendations developed from the ACCORD trial, which revealed a significantly increased rate of death in intensively-treated patients with DM and cardiovascular disease (The Action to Control Cardiovascular Risk

in Diabetes Study Group, 2008). An additional study of adults with T2DM found an increased risk of cardiovascular events (stroke, myocardial infarction, or death due to cardiovascular causes) in patients with an A1C of less than 6 or greater than 8 (Colayco, Niu, McCombs & Cheetham, 2011). Currently, the ADA recommends the individualization of A1C goals based on several factors, including age, comorbid conditions, and known cardiovascular disease (American Diabetes Association, 2014). As 14% of the dissertation study sample reported having cardiovascular disease, the rates of suboptimal glycemic control are not surprising.

Diabetes Symptoms

The sample reported a substantial number of diabetes symptoms. Ninety-six percent of subjects reported the presence of at least one symptom (ranging from "present but not troublesome" to "extremely troublesome"). Hyperglycemic symptoms were experienced by 80% of the sample, followed by cardiac symptoms (74% of subjects) and neuro-sensory symptoms (66% of subjects). Compared to several other studies of persons with T2DM, the dissertation study participants reported greater diabetes symptom burden (Table 30). However, one small study by Opsteen and colleagues (n=34 adults with T2DM, 38% female; Opsteen, Qi, Zinman & Retnakaran, 2012) reported greater overall symptom burden (*M*=2.3) than the dissertation study (*M*=1.11 ±0.77, 95% CI= 0.96 to 1.26). This is remarkable as the Opsteen study sample was slightly younger (59 vs. 63 years), with shorter duration of DM (5.9 vs. 12.6 years), less DM complications (e.g. 28% vs. 36% self-reported neuropathy), and better glycemic

control (A1C 7% vs. 7.9%). Due to the very small sample size in the Opsteen study, the findings should be considered preliminary and possibly spurious.

Diabetes symptom distress varied per subscale. In the neuro-sensory, cardiac, and hypoglycemic subscales, subjects reported higher more burdensome symptoms than other studies using the DSC-R (Table 30). Several studies using the DSC or DSC-R used a variety of scoring methods. The variable calculations made between-study comparisons challenging; therefore, Table 30 includes only the studies with same scoring as the dissertation study. In the ophthalmologic and hyperglycemic subscales, subjects' scores were consistent with other studies (Table 30). The literature demonstrates that diabetes symptoms are burdensome for patients with T2DM and can affect QOL. Physical symptoms, such as pain, sensory, and cardiovascular, are more common in patients over age 60; however, psychological symptoms such as negative mood or depression are greater in those younger than age 60 ($p<0.001$, Sudore et al., 2012). Patients with T2DM and depression experience approximately three times more symptom burden than patients with DM and no depression ($p<0.01$, Adriaanse et al., 2008). In the dissertation study, patients with a history of depression reported greater symptom burden (DSC total score 1.48 vs. 0.92, $t=-3.732$, $p<0.001$). Clearly, diabetes symptoms have an impact on QOL.

Table 30. Diabetes Symptoms in Other Studies Using the Diabetes Symptom Checklist-Revised (DSC-R)

Study	N	Sample Characteristics	Diabetes Symptom Checklist-Revised Subscales: Mean (SD)					TOTAL score M (SD)
			Neuro-Sensory	CV	Ophthalmologic	Hypo	Hyperglycemia	
McCormick, 2014	107		0.91 (1.03)	0.89 (0.84)	0.67 (0.93)	1.21 (1.18)	1.44 (1.07)	1.11(0.77)
Arbuckle, 2009	2023	Mean age 51 years, 42% female; 88% Caucasian; newly diagnosed w/ T2DM (US, Canada, Europe)	0.60 (0.82)	0.67 (0.79)	0.61 (0.87)	0.80 (1.00)	1.24 (1.15)	0.82 (0.71)
Kleefstra 2010[+]	18	Mean age 59 yrs., 28% female; DM duration 8 yrs.; 11% with ≥1 DM complication (Netherlands)						0.7 (0.4, 1.0)
Opsteen 2012[++]	34	Mean age 59 yrs., 38% female; DM duration 6 years; 28% with ≥1 DM complications (Canada)	0 (0-2.0)	0 (0-2.0)	0 (0-2.0)	0 (0-2.0)	2.0 (1-2.3)	2.3
Vadstrup 2011	143	Mean age 58 years, 40% female, DM duration 6.4 years; 33% with ≥1 DM complications (Denmark)	0.5 (0.7)	0.7 (0.7)	0.5 (0.8)	1.0 (1.0)	1.5 (1.1)	0.9 (0.6)

[+]Values presented are Median (25th percentile, 75th percentile) due to right-skewed distribution

[++] Values are Median with interquartile range; no range provided for total score; Additional subscales: Fatigue 2.0 (0-2.3), Cognitive 2.0 (1.5-2.3)

Mood Symptoms

In the overall sample, mood was not dissimilar from other studies of persons with diabetes. Three studies have used the WBQ-12 to analyze mood in subjects with T2DM (Table 31). None of the studies are from the US. Subjects in two studies had shorter disease duration (mean DM duration less than 6 years). The dissertation study's WBQ-12 results are most similar to those of Pouwer et al. (1999), whose subjects had a longer DM duration and at least one complication of DM. The presence of DM-related complications and/or longer disease duration is associated with lower psychological well-being and mood (Nicolucci et al., 2009; Savli & Sevinc, 2005). In the dissertation sample, mean reports of mood-related symptoms were as expected. Gender differences existed and are discussed below.

Table 31. Psychological Well-being in Other Studies Using the Well Being Questionnaire-12

Author	N	Sample Characteristics (all T2DM outpatients)	WBQ Scores: Mean (SD)			
			General well-being	Energy	Positive Well-Being	Negative Well-Being
McCormick, 2014			24.1(6.7)	6.6 (2.7)	7.5(3.0)	1.9 (2.2)
Pouwer et al., 1999	349	Mean age 51 years, 49% female; DM duration 16 years; Dutch with at least 1 complication of DM	24.4(7.2)	7.5 (3.0)	7.6(2.8)	2.7(2.9)
Reid et al., 2010	218	Mean age 54 years, 35% female, DM duration 5.4 years; Canadians treated with diet and/or oral medications (no insulin)	26.1(5.4)	--	--	--
Van den Donk et al., 2013	2217	Mean age 65 years, 43% female; DM duration 5.7 years; from 318 European clinics (4 centers)	25.0(6.3) to 28.5(5.9)	7.0(2.7) to 8.5(2.6)	8.0(2.9) to 9.4(2.5)	1.1(1.8) to 2.1(2.5)

Functional Performance

Subjects' functional performance was equal or greater than average. Subjects in the dissertation study reported physical and mental functioning at similar levels to other persons with DM. SF-12 normative data was developed from the National Survey of Functional Health Status (1998; n=14906), representing the non-institutionalized US adult population (Ware, Kosinski, Turner-Bowker & Gandek, 2002). In the dissertation study, physical functioning (SF-12 physical composite scores, *M*=41.47± 11.97) was very

similar to the diabetes normative data (*M*=41.52±11.07). Social functioning (SF-12 mental composite score) from the dissertation study (*M*= 50.93 ± 9.91) were slightly above normative data for persons with DM (*M*=47.28±10.72).

Diabetes self-management was similar to published instrument data. The mean SCI-R score in the dissertation study was 61.61(± 13.68). A study of 159 US adults with T2DM (88% Caucasian, 57% female, age 47±15 years, diabetes duration 13±12 years) revealed the mean score on the SCI-R to be 64.4 (SD=17.9; Weinger, Butler, Welch & LaGreca, 2005). Similar results were found in a study of 353 UK adults with T2DM (39% female, age 66±9 years, diabetes duration 17±7 years; mean SCI-R score 69.0±12.8; Khagram, Martin, Davies & Speight, 2013). As with other studies, subjects in the dissertation study reported a wide range of diabetes self-management performance (Range: 28.85-89.29).

Health Perceptions

The Appraisal of Diabetes Scale assesses patients' acceptance of DM and its related burdens. A higher score indicates a greater disease burden. In the dissertation study, subjects reported their DM as moderately challenging (*M*= 17.10 ± 4.46). In a study of adults with similar demographics to the dissertation study (n=94 Midwestern US outpatients with T2DM; mean age 61 years; 62% female), Poradzisz (2001) reported similar scores on the ADS (*M*=17.84 ±5.05). The original study using the ADS reported greater disease burden (*M*=18.65 ±4.04); however, all participants were male veterans from the VA outpatient clinic (Carey et al., 1991). The ADS assesses control, uncertainty,

effects of disease on life goals, and DM related distress. In the dissertation study, subjects reported these dimensions at expected levels.

Quality of Life

Participants in the dissertation study rated their QOL highly. This is consistent with other studies of persons with diabetes. The dissertation sample reported very high quality of life in three subscales: Social & Economic, Psychological & Spiritual, and Family. QOL was reported slightly lower in the Health and Functioning subscale, which may be expected due to the presence of DM complications in the dissertation sample. Other studies using the same instrument have reported overall means ranging from 20.5 to 23.40 (Table 32). This variability may be due to the diverse settings of the studies. The highest mean QLI scores (23.40±3.55) were reported in a study of Hispanic adults with T2DM, primarily immigrants from Mexico (74%) with an average of nine years living in the US (Hu, Wallace & Tesh, 2010). Duration of DM was 4.5 years (SD ± 0.25). These QOL findings are consistent with the findings of Naranjo and colleagues, who reported decreased QOL in in Black adults with DM but not in their Latino peers, despite greater perception of disease burden among Latinos (Naranjo, Hessler, Deol & Chesla, 2012). Acculturation was found to have a significant moderating effect on QOL. Shorter duration of DM has been linked to higher QOL (Narajo et al., 2012). These factors should be considered in comparing these QLI scores to the dissertation study findings. The dissertation study's sample mean is within the range of the other studies' findings. The QOL reported by participants was good and in accordance with existing data.

Table 32. Quality of Life in Other Studies Using the Quality of Life Index: Diabetes Version

Author	Sample Size	Sample Characteristics	QLI overall mean (SD)
McCormick, 2014	*107*		*21.81 (4.70)*
Hu, Wallace & Tesh, 2010	59	Mean age 49 years; 68% female; Hispanic outpatients in Southeast US	23.40 (3.55)
Lewko et al. 2013	71	Mean age 55 years; 52% female; Inpatients in Poland	Gp. 1: 20.5 (3.8) Gp. 2: 21.9 (4.5)
Poradzisz, 2001	94	Mean age 61 years; 62% female; T2DM outpatients in Midwest US	21.10 (4.38)

By examining QOL in a multidimensional manner, the construct is depicted more fully. The dissertation study subjects reported adequate HRQOL. Certain dimensions of QOL were rated highly. Study subjects reported better than average access to care, social support, mood, social functioning, and diabetes self-management. Other dimensions were equivalent to normative data, such as glycemic control, disease appraisal, and role functioning. In contrast, diabetes symptoms were rated poorly by subjects and were greater than several comparable studies.

The first study aim also examined using Pearson's correlations to describe the relationships between key study variables. Higher QOL was found with greater age, social support, general well-being, role functioning, and social functioning. The positive correlation between older age and quality of life is consistent with the higher mental QOL reported by older adults in several studies. In a study of 353 adults with T2DM, older adults (age > 65 years) reported better QOL and positive well-being despite lower energy and more DM complications than their younger peers (age ≤65 years; Speight,

Khagram & Davies, 2012). Similar findings were documented by a study of 191 adults with insulin-dependent DM (68% T2DM; Trief, Wade, Pine & Weinstock, 2003). When compared to middle-aged and young adults, older adults in the dissertation study reported significantly better DM coping and less DM-related distress, despite having worse physical functioning and role limitations. These findings are not specific to diabetes. According to the US Behavioral Risk Factor Surveillance System, older adults report better mental QOL, despite worse physical QOL and more self-ratings of "fair or poor" health (Zack, 2013). This may be a generational or experiential effect.

The dissertation study subjects reported worse QOL with higher levels of obesity, poor glycemic control, and diabetes-related complications and symptoms. Also, QOL was decreased in subjects who had poor acceptance of their disease as measured by the ADS. Individuals with a negative perception of their diabetes have reported lower QOL (Scollan-Koliopoulos et al., 2013). Insulin management and diabetes self-care were not significantly correlated with QOL. However, both correlations had low statistical power (0.49 and 0.34, respectively) per post-hoc power analysis (G*Power 3.1.6). Power should be 0.8 or greater to minimize the likelihood of a type II error (Field, 2009).

Finally, the first study aim described the gender differences in QOL and related study variables. There were no significant gender differences in ethnicity, duration of DM, social support, glycemic control (A1C), BMI, diabetes self-care, or acceptance of diabetes (ADS). Insulin management could not be analyzed according to gender due to insufficient numbers. Male and female subjects had some demographic differences.

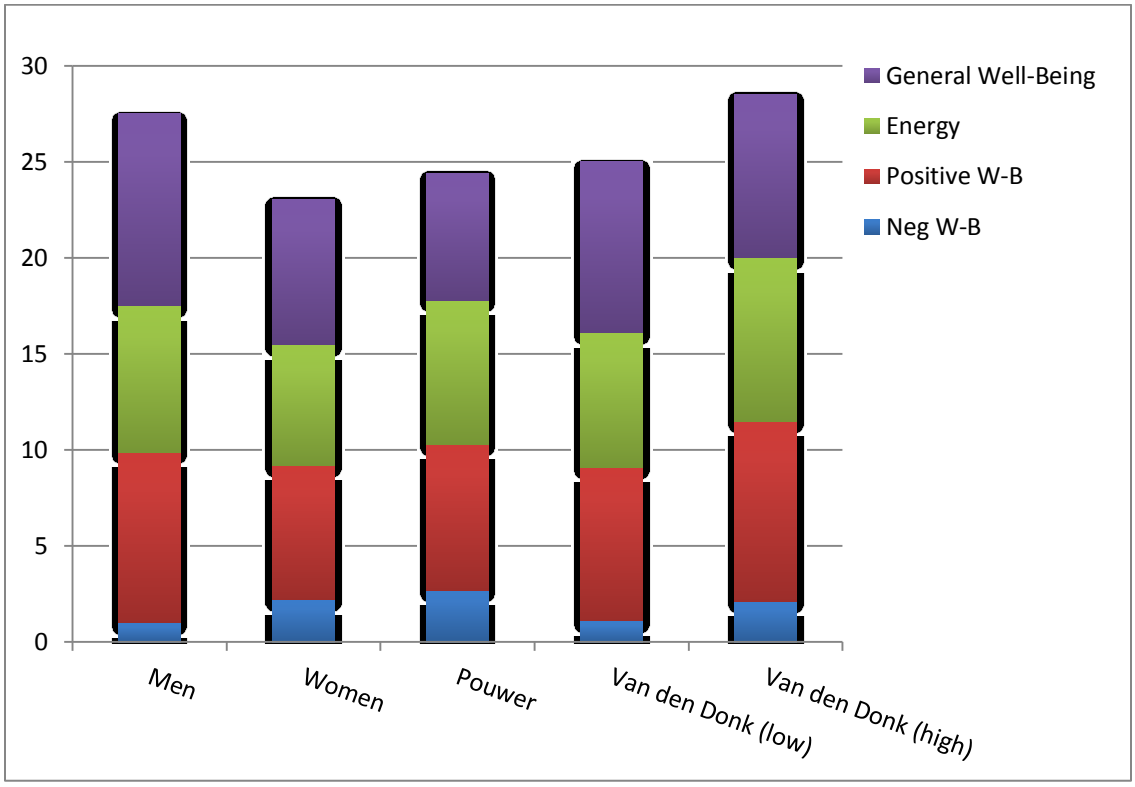
Males were older and most were married. Women were most likely to be non-partnered (divorced, never married, or widowed). This is significant because being married may provide a uniquely effective source of social support to some persons with diabetes. Positive spousal support has been linked to decreased diabetes distress, increased DSM behaviors, greater dietary adherence, and more physical activity (Dempster, McCarthy & Davies, 2011; Franks et al., 2012; Khan, Stephens, Franks, Rook & Salem, 2013; Stephens et al., 2013; Stephens, Rook, Franks, Khan & Lida, 2010). It should be noted however, wives have been shown to provide greater psychological support for their husbands with T2DM (Lida, Parris Stephens, Rook, Franks & Salem, 2010).

Health-related differences included both physical and psychological. Men reported a greater number of diabetes-related complications. Despite men having more complications, both genders reported equivalent amounts of diabetes-related symptoms. This means that women experienced more diabetes-related symptoms even with fewer diabetes complications. Numerous studies have documented greater diabetes symptoms in women. One large study (n=14206) found a 50% greater risk of painful neuropathic symptoms in women vs. men with T2DM (OR = 1.5, $p<0.0001$), despite less clinical neuropathy (19 vs. 23%, $p<0.0001$; Abbott, Malik, van Ross, Kulkarni & Boulton, 2011). Women with T2DM are also more likely than men to report symptoms of gastroparesis (OR = 1.838, $p<0.05$; Dickman, Wainstein, Glezerman, Niv & Boaz, 2014). Significant fatigue has been reported in women with T2DM (Fritschi et al., 2012).

Women also reported higher levels of cardiac symptoms, despite equal cardiac disease prevalence as male participants. This is consistent with the findings of Tamis-Holland and colleagues, who found that women with T2DM had more anginal symptoms than men but had less obstructive cardiac disease (Tamis-Holland et al., 2011; Tamis-Holland et al., 2013). Physical symptoms related to T2DM are different in women than in men.

Women in the dissertation study reported a greater prevalence of diagnosed depression than men (OR = 3.61, $p<.05$). Per meta-analysis, depression is twice as likely in people with DM as in their peers without DM (OR = 2.0, 95% CI 1.8-2.2; Anderson, Freedland, Clouse & Lustman, 2001). Depressive symptoms are even more common, reported by 44% of persons with DM in a large, multi-national study (Nicolucci et al., 2013). Depression is especially prevalent in women with diabetes. There is a two-fold increased likelihood of depressive symptoms in women with T2DM (Egede, 2007). In the dissertation study, male participants reported higher general well-being, energy, and positive well-being. When compared to data from other studies (Pouwer et al., 1999; Reid et al., 2010; Van den Donk et al., 2013; see table 31 above), both general and positive well-being were higher in dissertation study males. Female participants reported more negative well-being than men in the dissertation study; however, comparison with other studies (Pouwer et al., 1999; Van den Donk et al., 2013) reveals that this sample (men and women) had less or equivalent negative well-being. Details are provided in Figure 6. In addition to higher well-being, male subjects also reported higher levels of mental performance per the SF-12.

Figure 6. Well-Being by Gender



In addition to well-being, quality of life was also reported as lower by women in the dissertation study. In overall QOL and all subscales, women reported significantly lower quality of life than men. Gender differences in QOL have been reported in several studies. Compared to men, women with T2DM have lower QOL (Papadopoulos, Kontodimopoulos, Frydas, Ikonomakis & Niakas, 2007; Glasgow, Ruggiero, Eakin, Dryfoos & Chobanian, 1997) and more self-rated "unhealthy days" (OR = 0.66, $p<0.01$; Clifford, Collins, Buckley, Fitzgerald & Perry, 2013). QOL is especially lower in obese women with T2DM (Svenningsson, Marklund, Attvall, & Gedda, 2011). Women with depression and T2DM are particularly vulnerable to QOL effects. Gender is clearly an

important factor in understanding QOL in T2DM. Further research on this topic is essential.

Discussion of Aim 2: QOL Differences

Aim 2 hypothesized that QOL would differ according to type of insulin management. This study aim was not supported by the data--there were no significant differences in QOL based on type of insulin management. The one-way ANOVA achieved only 38 percent power, per post-hoc power analysis. Unfortunately, a sample size of 285 would be required to achieve acceptable power of 80 percent. Therefore, the second study aim was not statistically supported.

MANOVA testing was utilized to clarify the multiple interactions that may have affected QOL measurement in the study. The study model was used to select variables for MANOVA examination, and included type of glycemic management (oral, basal insulin, or basal-bolus insulin), glycemic control (Hemoglobin A1C), diabetes symptoms, mood (psychological well-being), diabetes self-care, acceptance of diabetes, and quality of life. Despite accounting for related dependent variables, QOL was still not shown to differ based on insulin management type.

Although QOL did not differ, MANOVA showed significant differences in diabetes self-care performed by subjects using basal-bolus insulin and those using oral medications alone. Subjects using basal-bolus insulin management scored higher on the SCI-R than subjects on oral medications only. It should be noted that the SCI-R accounts for different diabetes regimens. Persons completing the SCI-R may choose “not

applicable" for certain items, such as checking ketones, taking insulin and/or pills, or treating low blood glucose (Weinger, Welch, Butler & LaGreca, 2005). SCI-R scores represent patients' adherence to their prescribed DSM regimen. Therefore, subjects on basal-bolus insulin were actually performing a greater proportion of prescribed diabetes self-care. Even though these subjects had more required diabetes self-care activities, they still performed a greater proportion of the prescribed self-care.

MANOVA also revealed differences in glycemic control. Subjects taking insulin (basal only and basal-bolus) had worse glycemic control than those taking oral medication alone. Historically, insulin has been prescribed later in the disease course of T2DM, due to both physician and patient reluctance (Ratanawongsa et al., 2012; Nam, Chesla, Stotts, Kroon & Janson, 2010). Newer diabetes guidelines seek earlier treatment with insulin as needed to meet glycemic control goals (ADA, 2014; Shubrook, 2014). As a cross-sectional study, it is impossible to know the temporal correlation of insulin management and poor glycemic control in this sample.

After accounting for the effects of glycemic control and diabetes self-care with MANOVA, QOL did not vary based on insulin management. *Greater power would be required to make conclusions regarding the original study aim.*

Discussion of Aim 3: Predicting QOL

Multiple regression analysis was used to determine if type of glycemic management was predictive of HRQOL after controlling for covariates. First, simultaneous multiple regression tested the effects of five predictors on QOL. In this

regression, glycemic control, diabetes symptoms, and diabetes self-management were not significant predictors per beta weight analysis. Significant QOL predictors were general well-being and appraisal of diabetes. Examination of beta weights showed that general well-being positively predicted QOL ($\beta = .47$, $p<.001$). Appraisal of diabetes (ADS) negatively predicted QOL ($\beta = -.22$, $p<.05$). As a proxy measure for mood, it is clear that general well-being would predict QOL in a positive manner. Correlations between the WBQ and the mental health component of the SF-36 have been robust ($r=0.80$, $p<0.001$; McMillan, Bradley, Gibney, Russell-Jones & Sonksen, 2006 and $r=0.75$, $p<0.001$; Pouwer et al., 1999). The negative predictive relationship between the ADS and QOL was expected: poor disease acceptance has been linked to lower QOL ($r=-0.55$, $p<0.01$; Poradzisz, 2001).

A moderated model of diabetes self-care, general well-being, and QOL was tested by multiple regression analysis (Figure 3). The model showed significant effects on QOL by general well-being (main effect) and the interaction between general well-being and diabetes self-care. The relationship between general well-being and QOL is moderated by diabetes self-care. This effect is most clearly evident with low general well-being, where high self-care is related to a significantly higher QOL. The moderation effect of self-care is shown graphically in Figure 4.

These findings are consistent with descriptions of moderated models. A moderating variable is defined as a third variable that affects the relationship between two other variables (Baron & Kenny, 1986). A moderator is an independent variable

which affects the dependent variable (outcome) through interaction with the predictor variable. The predictor variable may or may not have a significant main effect on the outcome variable (Holmbeck, 1997). Traditionally, moderators are not antecedent or causal (Baron & Kenny, 1986). The cross-sectional nature of the dissertation study precludes temporal conclusions. The moderated model of this study should be considered preliminary. Further testing is required to understand the directionality of the relationship between general well-being, self-care, and QOL. However, these concepts are indisputably linked.

Summary of Major Findings

The major study findings are summarized as follows. First, examination of major study variables showed that the sample experienced satisfactory QOL and related domains. Compared to other studies of persons with diabetes, subjects reported above average access to care, social support, social functioning, diabetes self-management, overall QOL, and subscale QOL (Social & Economic, Psychological & Spiritual, and Family). Glycemic control, well-being (general and positive), role functioning, disease acceptance, and health and functioning subscale QOL were consistent with existing studies. However, study participants reported more diabetes symptoms, and less energy than their peers. Second, correlations revealed that QOL was positively influenced by age, social support, general well-being, role functioning, and social functioning. QOL was negatively influenced by obesity, poor glycemic control, disease acceptance, and diabetes-related complications and symptoms. Third, when analyzed

by gender, women reported lower well-being and greater negative well-being, as well as lower QOL. Female participants were also more likely to have diagnosed depression and report more diabetes symptoms, despite less prevalence of diabetes-related complications

Fourth, the study was designed to evaluate the relationship between insulin management strategy and QOL. Both ANOVA and MANOVA failed to provide statistical evidence to support this relationship. The study was insufficiently powered to declare negative findings and will require further testing before conclusions can be made. However, statistical modeling revealed that disease acceptance and general well-being are significant predictors of QOL. Per multiple regression analysis, greater disease acceptance and general well-being are positive predictors of QOL.

Finally, a moderated model of diabetes self-care, general well-being, and QOL was examined by multiple regression analysis. The regression model revealed that self-care is a moderator in the relationship between general well-being and QOL. Analysis by gender revealed the moderating effect of self-care is most significant in women in the presence of negative mood. Clearly, this area is grounds for future research.

Study Limitations

This study has limitations to both internal and external validity. Internal validity is limited by several factors. First, the non-experimental design affects the internal validity of the findings. As a cross-sectional, observational study, no conclusions of causality can be made. Second, the study is limited by selection bias. The participants

were a non-random convenience sample. A substantial minority of the sample (43%) was recruited from a database of persons interested in diabetes and depression studies. This may have resulted in a disproportionate share of women with depressive symptoms in the sample. Third, instrumentation may have affected internal validity. The questionnaires rely upon accurate self-assessment and honest reporting. It is impossible to know if subjects over- or under-estimated parameters such as diabetes self-management activities or negative mood symptoms. Fourth, although many confounding variables were minimized through exclusion criteria, not all could be eliminated. For example, duration of DM and presence of co-morbidities (heart disease, chronic pain) were greater in the basal-bolus insulin group. Disease duration and co-morbid illness have potential QOL effects. Due to uneven distribution of these factors among insulin management groups, it is impossible to rule out confounding effects on QOL. Additionally, the study had low power due to a small sample size and lower than expected effect size. Finally, although minimized, any missing data may affect internal validity.

External validity of the study was also affected by several factors. Most of the threats to external validity are related to sampling; the sample was fairly homogenous. Racial minorities were not sufficiently represented in the sample, nor younger adults. Non-English speakers were excluded from the study. Recruitment was done through a database of prior study volunteers, outpatient clinics in the Midwest US, and via the internet. This means that the sample represented only people with media, clinic, and/or

internet access. All participants were volunteers; this fact limits generalizability to those who voluntarily participate in research. This study's limitations should be noted when interpreting the findings.

Nursing Implications

Nurses encounter persons with DM in nearly every healthcare setting. As worldwide rates of T2DM are only expected to increase, it is essential for nurses to understand QOL in DM. The study revealed gender differences in QOL. Women in the study reported lower QOL and negative well-being, as well as more cardiac symptoms than men. This is an important finding for nursing clinical practice. Nurses should be aware of the higher risk of depressive symptoms in women with diabetes and the resulting impact on QOL. Study subjects reporting lower general well-being and less diabetes self-management activities experienced lower QOL. Although the study findings do not demonstrate causality, nursing assessment of persons with DM should include mood and performance of DSM behaviors. Nurses are very capable at recognizing depressive symptoms and diabetes-related distress (Pouwer, Beekman, Lubach & Snoek, 2006). Because women are at greater risk for depressive symptoms (Egede, 2007), they are at particular risk for lower QOL and self-care. Nurses should be aware of the relationship between mood, DSM practices and glycemic control. Nursing interventions may include reinforcement of diabetic teaching, mood assessment, and facilitating treatment of depression. Nurse-led psychoeducational group therapy for depressed women with T2DM has been successful (Penckofer et al., 2012). A minimal

psychological intervention by nurses has been shown to modestly improve glycemic control, diabetes symptoms, and diabetes-related distress (Lamers, Jonkers, Bosma, Knottnerus & van Eijk, 2011). Patients who report decreased DSM practices and lower mood are at risk for loss of glycemic control. Nurses have the potential to minimize this risk.

Future Research

This study provides inspiration for future research. A larger study should be conducted to confirm the potentially negative findings. Ideally, the larger study would utilize a greater sample size and control for confounding factors such as DM duration and co-morbidities with case-controls per insulin management strategy. Other future studies could change the design or population. A longitudinal study of patients before and after initiation of basal-bolus insulin therapy would provide a more rigorous evaluation, as patients would serve as their own control subjects. Subjects could be tested at 6 and 12 months after basal-bolus insulin initiation. Additional studies could also focus on different age groups. A study of insulin management strategies and QOL should be conducted in young adults with T2DM. The correlation between older age and higher QOL could be further explored with qualitative research such as interviews or focus groups of older adults with T2DM. This would provide greater insight into the details of the age-QOL relationship. Future studies should include non-English speakers as well as teenagers with T2DM.

The moderating effect of DSM on well-being and QOL is grounds for future research. Future studies to explore causality and temporal precedence of these variables are crucial. One study could examine well-being and QOL in subjects before and after intense DSM education programs, with a longitudinal follow-up. Most importantly, studies should be conducted to explore the gender differences in the effect of self-care on negative well-being and QOL. Studies sufficiently powered to detect the effects of self-care in women are seminal. Qualitative studies, such as focus groups, could facilitate greater understanding of self-care in women with diabetes and negative mood. As the rates of type 2 diabetes continue to rise, future research is the key to understanding the multiple dimensions of quality of life for all persons with diabetes.

APPENDIX A

SUPPLEMENTAL LITERATURE REVIEW

Database Search Strategy

#	Search terms	Operator	Prior Search	Results (PubMed)
S3	(diabetes mellitus, type 2) or (MeSH Major Topic “diabetes mellitus, type 2”)	AND	Insulin	66256
S4	(quality of life) or (QOL) or (“quality of life”, MeSH Major Topic, MeSH Term)	AND	S3	1458
S9	(“insulin infusion systems”, MeSH Major Topic, MeSH Term) or (CSI) or (Continuous subcutaneous insulin) or (MDI) or (multiple daily)	AND	S4	150
Limits: 2009-2014, English language, human				71
After review of titles & abstracts				29
After review of full-text articles				12

Study	Sample (all T2DM unless specified)	Design	Outcomes	Findings
Banerjee, Maji & Baruah, 2013 *A1chieve sub-study* India	N=343 Age: 53 yrs. 41% female DM duration: 9 yrs.	Longitudinal (24 wks.) Observational Analog basal-bolus initiation 75% of sample insulin-naïve at baseline	Glycemic Control Hypoglycemia QOL (EQ-5D)	**Huge** A1C improvements (9.3 to 7.7%, p<.001): Less hypoglycemia in pts on insulin prior to study (p<.001) ↑QOL in both insulin-naïve and experienced groups (p<.001)
Dieuzeide et al., 2014 *A1chieve sub-study* 28 countries	N=1024[t] Age 56±13 yrs. 52% female DM duration: 10±8 yrs. [t] Note: only 52% (533) remained in study (others lost to follow-up)	Longitudinal (24 wks.) Observational MDI to premix analogs (N=770 Reg-NPH, N=136 Reg-Lantus, N=104 analog basal-bolus)	Glycemic Control Hypoglycemia QOL (EQ-5D)	Huge A1C improvements (2%, p<.001) Less hypoglycemia, esp. in NPH group (p<.001). QOL greater after starting premix(p<.001)
Hajos et al., 2012 Netherlands	N=447 w/T2DM Age: 59±11 yrs. 49% female DM duration: 11 yrs.	Longitudinal (6 mo.) Started basal-bolus insulin (baseline: basal only or premix)	Glycemic control Fear of hypoglycemia Diabetes symptoms (DSC-r) QOL (WHO-5 well-being)	DM Symptoms improved (p<0.001) QOL/emotional well-being improved (p<0.001)

Study	Sample (all T2DM unless specified)	Design	Outcomes	Findings
Hermanns et al., 2012 Germany	N=167 Age: 64±8 yrs. 45% female DM duration: 14±7 yrs.	RCT (6 months) Intensive basal-bolus education vs. standard	Glycemic Control QOL (SF-12) DM distress (PAID) Diabetes Knowledge Self-care activities	Exp. Gp. had less DM distress (p<.001), improved PCS of SF-12 (p<.05), improved diabetes knowledge
Levin et al., 2011 U.S.	N=197 Age: 56 yrs. 54% female DM duration: 13 yrs.	RCT (9 months) Basal-bolus vs. premix	Glycemic control QOL (DQOL, EQ-5D) Hypoglycemia Cost-effectiveness Work Productivity & Activity	Exp. gp.: less work days missed (p<.05), more cost-effective No signif. changes in QOL
Opsteen et al., 2012 Canada	N=34 Age: 59 yrs. 38% female DM duration: 6±7 yrs.	Longitudinal (8 weeks) Short-term intensive (basal-bolus) insulin therapy	Glycemic control QOL (SF-36, DQOL) Diabetes Symptoms (DSC-r)	SF-36 improved: PCS (p<.01), MCS (p<.05) DQOL “DM worries” subscale improved (p<.01) Less DM symptoms (p<.05)
Peyrot & Rubin, 2011 U.S.	N=618 Age: 56±10 yrs. 53% female DM duration: 13±7 yrs.	RCT (45 weeks) Basal-bolus (inhaled bolus insulin) vs. premix	Glycemic control QOL (SF-36) Treatment Satisfaction (IITQ)	No signif. changes in QOL Less DM worries in B-B group

Study	Sample (all T2DM unless specified)	Design	Outcomes	Findings
Peyrot et al., 2011 U.S.	N=54	Longitudinal (16 weeks) CSI initiation	Glycemic ctrl (A1C, CGMS) QOL (EQ-5D) DM Symptoms (DSC-r) Treatment Satisf. (IDSRQ)	No change in QOL overall Less DM symptoms (p<.05)
Rubin et al., 2010 U.S.	Age: 57±10 yrs. 50% female DM duration: 13±6 yrs.	Longitudinal (16 weeks) All started CSI (differed by baseline RX: N=17 orals, N=17 basal, N=20 basal-bolus		Oral gp.: No QOL or Sx changes Basal and B-B groups: QOL improved (p<.05), less DM symptoms (p<.05)
Shah et al., 2011 *A1chieve study* 28 countries (33% South Asia; 22% Middle East)	N=66,726 Age: 54±12 yrs. 44% female DM duration: 8±6 yrs. 67% of sample insulin-naïve at baseline	Longitudinal (24 weeks) Observational Routine analog initiation or intensification (to premix, basal, or basal-bolus)	Glycemic Control Hypoglycemia QOL (EQ-5D)	**Huge** A1C improvements (9.5 to 7.4%, p<.001): QOL improved in all subgroups (p<.001) & countries (p<.001) in similar amounts
Testa et al., 2012 U.S.	N=388 (80% T2DM) Age: 54±11 yrs. 53% female DM duration: 16±9 yrs.	RCT: Crossover (24 weeks) Analog basal-bolus vs. premix	Glycemic control & variability (A1C, CGMS) Treatment satisfaction QOL (Author's own instrument)	With basal-bolus: Better QOL (p<.001) ↓ symptom distress (p<.0001) Better glycemic control and variability (p<.0001)
Vinagre et al., 2013 Spain	N=37 Age 65±8 yrs. 38% female DM duration 18±8 yrs.	Longitudinal (6 months) Basal only or premix (89%) started basal-bolus insulin	Glycemic control Severe hypoglycemia QOL (DQOL)	No change in QOL (all subscales)

APPENDIX B

PARTICIPANT SCREENING TOOL

Date of initial call: Name: Phone:

Screening Questions: Inclusion	Yes	No*
1. Are you at least 18 years old?		
2. Do you have diabetes?		
3. Do you have "adult-onset" / "type 2" diabetes?		
4. Do you take medication for your diabetes at least one time a day?		
5. Have you been taking diabetes medicine for at least six months?		
6. Have you had the same diabetes medication schedule for at least 3 months? (for example, insulin doses per day)		
7. Are you able to read, write, and speak English?		

*A "**No**" answer disqualifies a subject from study enrollment

Screening Questions: Exclusion	Yes**	No
1. Are you pregnant right now?		
2. Do you have sickle cell disease?		
3. Have you been treated for cancer (chemo or radiation) in the last 3 years?		
4. Do you have HIV (Human-Immunodeficiency Virus) or AIDS?		
5. Do you have Alzheimer's or dementia?		
6. Do you have bipolar disorder or manic depressive disorder?		
7. Do you have schizophrenia or schizoaffective disorder?		
8. Do you any other major psychiatric disorder? (depression is acceptable)		
9. Do you have fibromyalgia?		

A "Yes**" answer disqualifies a subject from study enrollment.

To assure appropriate distribution of subjects among diabetes management groups:

Screening Questions: Verification	Yes	No
1. Do you take insulin?		
2. How many times per day do you take insulin:		
a. Once a day?		
b. Two times a day?		
c. Three or more times a day?		
3. Do you have an insulin pump?		
4. Do you take short-acting insulin (i.e., Regular, Humalog, Novolog, Apidra)?		
5. Do you take long-acting insulin (i.e. NPH, Lantus, Levemir, Lente)?		

Can we mail you the study packet? No / Yes	If yes, address:
Can I call you (with message if you are not home) or email you to see if you got the booklet? No / Yes	
Gender: M / F	How recruited:
Accepted into study: No / Yes	If yes, Subject #:
Contact attempts:	

APPENDIX C

RECRUITMENT LETTER

Marcella Niehoff School of Nursing
2160 South First Avenue
Maywood, Illinois 60532

June 14, 2012

Dear Sir or Madam,

I am a graduate student in nursing at Loyola University Chicago. I am conducting a research project on quality of life in persons living with type 2 diabetes. Dr. Susan Penckofer is my supervisor during this study and has given me permission to inform you about this project. The study will consist of a questionnaire booklet and finger-stick blood test for hemoglobin A1C which you will complete at home and return to me in a pre-paid envelope. It will take about one hour to complete. You will be informed of your hemoglobin A1C test results. Upon completion of the survey, you will also receive a $10 gift card.

The results of this project will be used to help me complete my graduate studies. Through your participation, I hope to understand more about the quality of life in people with type 2 diabetes. The results will hopefully be useful for doctors and nurses who care for people with diabetes. I also hope to share my results by publishing them in a scientific journal.

There are no risks to you in participating in this survey, beyond what you already experience in everyday life with diabetes. Your responses will be kept confidential. Your name will not appear in any study results.

If you are interested in learning more about the study or participating in the study, please call me at **(630)-219-1331**. I appreciate your time and help! Thank you.

Sincerely,

Sandra McCormick, RN, BSN
Graduate Student in Nursing
Loyola University Chicago

APPENDIX D

STUDY FLYER

IRB LU# 204151

Volunteers Needed for Research Study:

Quality of Life in Type 2 Diabetes

- The purpose of the study is to understand the quality of life for people with type 2 diabetes
- The study is open to all English-speaking adults age 18 and older who take medications (pills and/or insulin) for type 2 diabetes
- The study is not a treatment. Participants will fill out a questionnaire booklet and complete a finger-stick blood test and return the study packet by mail. You will receive a $10 gift card and your hemoglobin A1C result.

Principal Investigator: Sandra McCormick, RN, BSN
Graduate Nursing Student
Loyola University Chicago

Faculty Advisor: Susan Penckofer, RN, PhD

If interested, please contact:

Sandra McCormick at (630)-219-1331

APPENDIX E

STUDY INSTRUCTIONS LETTER

Marcella Niehoff School of Nursing
2160 South First Avenue
Maywood, Illinois 60532

Dear Sir or Madam,

Thank you for taking the time to participate in my research study. The information you provide for the study is very valuable. It is important to complete the survey and blood test as soon as possible. Once the survey packet and blood test are complete, you will mail both by U.S. Mail in the pre-paid envelope within 10 days. Please feel free to contact me by phone (information below). Instructions for completing the study materials are provided below.

1. **Blood test (Hemoglobin A1C):**
   - Detailed instructions on how to complete the blood test are on the next page
   - Sign and date the "Test Authorization Form".
   - Blood test should take less than 5 minutes to collect
   - Allow the blood test to dry for <u>at least</u> 30 minutes before placing in envelope.

2. **Survey (Questionnaire booklet):**
   - Fill out the questionnaire booklet. It will take about 1 hour to complete.
   - If you have questions, please contact me at the number below.
   - If you do not want to answer a question, you can leave the question blank.

3. **Place your completed booklet and blood test card in the large stamped envelope. Send by U.S. Mail.**

You may contact me at (630)-219-1331 or my faculty advisor (Susan Penckofer, 708-216-9303) with any questions or concerns. If you have any questions concerning your rights as a research participant, you may contact Dr. Kenneth Micetich, Chairman, Institutional Review Board for the Protection of Human Subjects-Medical Center (708-216-4608).

Thank you again for your time and effort in participating in my study!

Sincerely,
Sandra McCormick, RN, BSN
Graduate Nursing Student
Loyola University Chicago

HEMOGLOBIN A1c COLLECTION INSTRUCTIONS

PLEASE READ THOROUGHLY

Remember to complete all your personal information on the Hemoglobin A1C Test Authorization Form. Please read and provide your signature and date under the Patient Consent in order to approve your sample for testing. Heritage labs will not complete any testing without your signature and date.

Toll-free ReliOn customer support: **1-888-764-2384**

1. Review the Contents of Your Kit

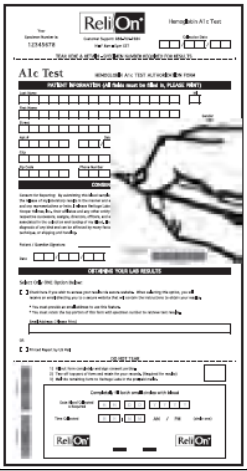
Your test kit contains:

- Collection instruction sheet
- Hemoglobin A1C Test Authorization & Collection Form
- Lancet
- Alcohol Pad
- Gauze Pad
- Adhesive Bandage
- Postage Paid Return Envelope

2. Fill Out the Hemoglobin A1C Test Authorization Form

The Hemoglobin A1C Test Authorization Form has already been completed by the researcher.

Please **sign and date** the test form, or testing cannot be done.



3. Prepare Hands

Rinse hands in warm tap water. Clean the selected puncture site with the alcohol pad and dry it with the gauze pad.

4. Stimulate Blood Flow

Stimulate blood flow to the selected finger by letting your hand hang down at your side for 15-20 seconds. Shake your hand back and forth several times.

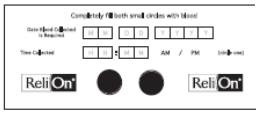
5. Use the Lancet Provided

Using the lancet provided, remove the cap, place palm up and position lancet on finger. Press down on lancet to puncture site. Wipe off the first blood drop with the alcohol pad.

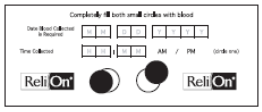
6. Blood Should Begin to Flow

Blood should begin to flow freely. Place a LARGE free-flowing drop of blood on each circle of the Collection Form as shown. Do NOT place one drop of blood on top of the other. If blood flow stops, wipe with alcohol pad again to assist blood flow.

CORRECT

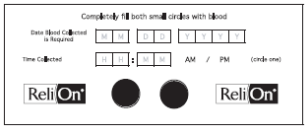


INCORRECT



7. Let the Blood Spot Air-Dry

Let the blood spot air-dry for at least 30 minutes. Make sure spot is dry before folding the Test Form.



8. Mailing Instructions

- Place the Hemoglobin A1C Test Authorization form into the postage-paid return envelope.
- Mail the sample within three days of collecting the blood sample.

Response Card (attached to front of questionnaire booklet)

Please circle the answer to the questions and return this card with your packet.		
1. You can call me if you have questions about my booklet.	Yes	No
2. I would like to receive my Hemoglobin A1C results.	Yes	No
3. I would like to receive my "thank you" $10 gift card.	Yes	No
My initials: _____	ID # _____	

APPENDIX F

SELF-REPORT QUESTIONNAIRES

1. What is your birth date?

_____/_____/_____

Month / Date / Year

2. What is your gender?

1. □ Male
2. □ Female

3. What is your ethnicity?

1. □ Hispanic
2. □ Non-Hispanic

4. What is your race?

1. □ American Indian or Alaskan Native
2. □ Asian or Pacific Islander
3. □ Black or African-American
4. □ White
5. □ Other

5. What is your marital status?

1. □ Never Married
2. □ Married
3. □ Separated
4. □ Divorced
5. □ Widowed

6. Please check your highest level of education:

1. □ Less than 9th grade
2. □ 9th to 12th grade, no diploma
3. □ High school graduate (includes GED)
4. □ Some college, no degree
5. □ Associate degree
6. □ Bachelor's degree
7. □ Graduate degree

7. Please indicate your total household income:

1. □ Less than $9,999
2. □ $10,000 to $14,999
3. □ $15,000 to $19,999
4. □ $20,000 to $29,999
5. □ $30,000 to $39,999
6. □ $40,000 to $49,999
7. □ $50,000 to $59,999
8. □ $60,000 to $69,999
9. □ $70,000 and over

8. What is your employment status?

1. □ Working full time, 35 hours or more per week
2. □ Working part-time, less than 35 hours per week
3. □ Unemployed or laid off and looking for work
4. □ Unemployed and not looking for work
5. □ Homemaker
6. □ In School
7. □ Retired
8. □ Disabled, not able to work
9. □ Other, please specify:

_____

Health Questionnaire

1. What is your height? _____ feet _____ inches
2. What is your weight? _____ pounds
3. What year were you told that you have diabetes? _____
4. Do you take pills for your diabetes?

   1. □ No 2. □ Yes, name of medicine(s): _____

5. Do you take insulin for your diabetes?

1. □ No	2. □ Yes →	5a. How many times a day do you usually take your insulin? (check ONE box)
↓		1. ☐ Once a day
		2. ☐ Twice a day
		3. ☐ Three times a day
		4. ☐ Four (or more) times a day
		5. ☐ I use an infusion pump
		5b. How long have you taken insulin? _____ years
		5c. Do you take short-acting insulin (Humulin Regular, Humalog, Novolog, Apidra)? 1. □ No 2. □ Yes
		5d. Do you take long-acting insulin (NPH, Lantus, Levemir, Lente)? 1. □ No 2. □ Yes

6. Do you take Byetta (exenatide) injection for your diabetes?

   1. □ No
   2. □ Yes

7. In the last **week**, how many times have you experienced hypoglycemia? _____
8. In the past **year**, how many times have you experienced hypoglycemia requiring the help of another person? _____

9. Have you ever been told you have depression?
    1. □ No
    2. □ Yes
10. Have you ever been treated for depression?
    1. □ No
    2. □ Yes
11. Are you taking medication for depression?
    1. □ No
    2. □ Yes, name of medicine(s):

       _____
12. Which of the following medical problems do you have?
    Check off those that apply to you—even if treated

	a.	Asthma		m.	Depression
	b.	Chronic Obstructive Pulmonary Disease or Emphysema		n.	Anxiety
	c.	Angina		o.	Panic Disorder
	d.	Congestive Heart Failure		p.	Vision problems (cataracts, glaucoma, macular degeneration)
	e.	High Blood Pressure (Hypertension)		q.	Hearing impairment (very hard of hearing, even with hearing aids)
	f.	Heart Disease		r.	Arthritis (rheumatoid or osteoarthritis)
	g.	Heart Attack (Myocardial Infarction)		s.	Degenerative disc disease (back problems, spinal stenosis, severe back pain)
	h.	Neurological Disease (Multiple sclerosis, Parkinson's)		t.	Sleep apnea
	i.	Stroke, Mini-Stroke, or Transient Ischemic Attack (TIA)		u.	HIV or AIDS
	j.	Peripheral Vascular Disease		v.	Fibromyalgia
	k.	Cancer		w.	Chronic Pain
	l.	Sickle Cell Disease		x.	Other:

13. Have you ever had any of the following procedures related to your heart? (circle one number on each line)

	No	Yes
a. Coronary Artery Bypass Surgery (Open Heart Surgery)	1	2
b. Coronary angioplasty ("Balloon" Heart Procedure)	1	2
c. Cardiac stent placed	1	2

14. Do you have any of the following? (circle one number on each line)

	No	Yes
a. Peripheral vascular disease (poor circulation to the legs)	1	2
b. Intermittent claudication (cramping in the legs after exercise)	1	2
c. Peripheral neuropathy (nerve problems causing numbness, tingling, or burning in the feet or hands)	1	2
d. Foot ulcers (wounds that do not heal)	1	2

15. Have you ever had an amputation of a part of your leg or foot for a poorly healing sore or poor circulation? (NOT due to an injury or accident: car crash, power tool injury, war injury, etc.)—Circle one number on each line.

	No	One (right side)	One (left side)	Both
a. Toes	1	2	3	4
b. Part of a foot or feet	1	2	3	4
c. Leg below knee	1	2	3	4
d. Leg above knee	1	2	3	4

16. Have you ever have any of the following eye problems? (circle one number on each line)

	No	Yes/ One eye	Yes/Both Eyes
a. Cataracts	1	2	3
b. Glaucoma	1	2	3
c. Detached Retina	1	2	3
d. Blurred vision (not corrected by eyeglasses)	1	2	3
e. Retinopathy (diabetic eye disease)	1	2	3
f. Laser eye surgery	1	2	3

17. Do you have the following medical problems? (circle one number on each line)

	No	Yes
a. Kidney failure?	1	2
b. Renal insufficiency or nephropathy?	1	2
c. Have you ever been on kidney dialysis?	1	2
d. Have you ever been told you have diabetic gastroparesis?	1	2
e. Do you vomit (throw up) after eating large meals?	1	2
f. Men Only: Do you have difficulty getting or maintaining an erection?	1	2

Brief-Chronic Illness Resources Survey (CIRS)

The following questions ask about a variety of different resources that people may use to manage their illness. For each item, select the number that best indicates your experience over the ***past 6 months***.

Over the past ***6 months***, to what extent:	Not at all	A little	A moderate amount	Quite a bit	A great deal
1. Has your doctor involved you as an equal partner in making decisions about illness management strategies and goals?	☐1	☐2	☐3	☐4	☐5
2. Has your doctor or other health care advisor listened carefully to what you had to say about your illness?	☐1	☐2	☐3	☐4	☐5
3. Has your doctor or other health care provider thoroughly explained the results of test you had done (e.g., cholesterol, blood pressure, or other laboratory tests?	☐1	☐2	☐3	☐4	☐5
4. Have family or friends exercised with you?	☐1	☐2	☐3	☐4	☐5
5. Have you shared healthy low-fat recipes with friends or family members?	☐1	☐2	☐3	☐4	☐5
6. Family or friends bought food or prepared food for you that were especially healthy or recommended?	☐1	☐2	☐3	☐4	☐5
7. Have you focused on the things you did well to manage your illness instead of those you did not?	☐1	☐2	☐3	☐4	☐5
8. Have you thought about or reviewed how you were doing in accomplishing your disease management goals?	☐1	☐2	☐3	☐4	☐5
9. Have you arranged your schedule so that you could more easily do the things you needed to do for your illness?	☐1	☐2	☐3	☐4	☐5
10. Have you walked or exercised outdoors in your neighborhood?	☐1	☐2	☐3	☐4	☐5
11. Have you walked or done other exercise activities with neighbors?	☐1	☐2	☐3	☐4	☐5

Over the past ***6 months***, to what extent:	Not at all	A little	A moderate amount	Quite a bit	A great deal
12. Have you eaten at a restaurant that offered a variety of tasty, low-fat good choices?	☐1	☐2	☐3	☐4	☐5
13. Have you gone to parks for picnics, walks, or other outings?	☐1	☐2	☐3	☐4	☐5
14. Have you read articles in newspapers or magazines about people who were successfully managing a chronic illness?	☐1	☐2	☐3	☐4	☐5
15. Have you had health insurance that covered most of the costs of your medical needs including medicine?	☐1	☐2	☐3	☐4	☐5
16. Have you seen billboards or other advertisements that encouraged not smoking, low-fat eating, or regular exercise?	☐1	☐2	☐3	☐4	☐5
17. Have you attended free or low-cost meetings (for example, Weight Watchers, church groups, hospital programs) that supported you in managing your illness?	☐1	☐2	☐3	☐4	☐5
18. Have you volunteered your time for local organizations or causes?	☐1	☐2	☐3	☐4	☐5
19. Have you attended wellness programs or fitness facilities?	☐1	☐2	☐3	☐4	☐5
20. Have you had a flexible work schedule that you could adjust to meet your needs? *(Leave blank if you don't work.)*	☐1	☐2	☐3	☐4	☐5
21. Has your workplace had rules or policies that made it easier for you to manage your illness (such as no smoking rules or time off work to exercise)? *(Leave blank if you don't work.)*	☐1	☐2	☐3	☐4	☐5
22. Have you had control over your job in terms of making decisions and setting priorities? *(Leave blank if you don't work.)*	☐1	☐2	☐3	☐4	☐5

Self Care Inventory-Revised Version (SCI-R)

This survey measures what you *actually do*, not what you are advised to do. How have you followed your diabetes treatment plan in the last 1-2 months?

	Never ↓	Rarely ↓	Sometimes ↓	Usually ↓	Always ↓	
1. **Check blood glucose with monitor**	1	2	3	4	5	
2. **Record blood glucose results**	1	2	3	4	5	
3. **If type 1: check ketones when glucose level is high**	1	2	3	4	5	Have type 2 diabetes
4. **Take the correct dose of diabetes pills or insulin**	1	2	3	4	5	Not taking diabetes pills or insulin
5. **Take diabetes pills or insulin at the right time**	1	2	3	4	5	Not taking diabetes pills or insulin
6. **Eat the correct food portions**	1	2	3	4	5	
7. **Eat meals/snacks on time**	1	2	3	4	5	
8. **Keep food records**	1	2	3	4	5	
9. **Read food labels**	1	2	3	4	5	
10. **Treat low blood glucose with just the recommended amount of carbohydrate**	1	2	3	4	5	Never had low blood glucose
11. **Carry quick acting sugar to treat low blood glucose**	1	2	3	4	5	
12. **Come in for clinic appointments**	1	2	3	4	5	
13. **Wear a Medic Alert ID**	1	2	3	4	5	
14. **Exercise**	1	2	3	4	5	
15. **If on insulin: Adjust insulin dosage based on glucose values, food, and exercise**	1	2	3	4	5	Not on insulin

Diabetes Symptom Checklist

Instructions

Please circle whether you have experienced the symptom or not in the last 4 weeks, today included. If you circled "yes" then indicate to what extent the symptom listed has caused you discomfort by circling the number that most closely reflects your experience.

If a symptom did not occur, please circle "No" in the column "DID SYMPTOM OCCUR"

EXAMPLE

		DID SYMPTOM OCCUR?	**THE SYMPTOM DID OCCUR AND WAS ……TROUBLESOME TO ME**				
			Not at all	A little	Moderately	Very	Extremely
Sore throat?	No						
	Yes	→→→→	1	(2)	3	4	5

This answer means: **In the last 4 weeks I did have a sore throat and it was a little troublesome to me**.

How much trouble have these symptoms given you over the last 4 weeks?

	DID SYMPTOM OCCUR?	**THE SYMPTOM DID OCCUR AND WAS ……TROUBLESOME TO ME**				
		Not at all	A little	Moderately	Very	Extremely
1. Lack of energy?	No Yes→→→→	1	2	3	4	5
2. Aching calves when walking?	No Yes→→→→	1	2	3	4	5
3. Numbness (loss of sensation) in the feet?	No Yes→→→→	1	2	3	4	5
4. An overall sense of fatigue?	No Yes→→→→	1	2	3	4	5
5. Shortness of breath at night?	No Yes→→→→	1	2	3	4	5

	DID SYMPTOM OCCUR?	**THE SYMPTOM DID OCCUR AND WAS ……TROUBLESOME TO ME**				
		Not at all	A little	Moderately	Very	Extremely
6. Sleepiness or drowsiness?	No Yes→→→→	1	2	3	4	5
7. Difficulty concentrating?	No Yes→→→→	1	2	3	4	5
8. Moodiness?	No Yes→→→→	1	2	3	4	5
9. Numbness (loss of sensation) in the hands?	No Yes→→→→	1	2	3	4	5
10. Persistently blurry vision (even with glasses on)?	No Yes→→→→	1	2	3	4	5
11. Tingling sensations in arms or legs at night?	No Yes→→→→	1	2	3	4	5
12. Being very thirsty?	No Yes→→→→	1	2	3	4	5
13. Palpitations or pounding in the heart region?	No Yes→→→→	1	2	3	4	5
14. Deteriorating vision?	No Yes→→→→	1	2	3	4	5
15. Burning pain in the calves at night?	No Yes→→→→	1	2	3	4	5
16. Dry mouth?	No Yes→→→→	1	2	3	4	5
17. Increasing fatigue during the course of the day?	No Yes→→→→	1	2	3	4	5
18. Flashes or black spots in the field of vision?	No Yes→→→→	1	2	3	4	5
19. Irritability just before a meal?	No Yes→→→→	1	2	3	4	5
20. Fatigue in the morning when getting up?	No Yes→→→→	1	2	3	4	5
21. Shooting pains in the legs?	No Yes→→→→	1	2	3	4	5
22. Alternating clear and blurred vision?	No Yes→→→→	1	2	3	4	5

	DID SYMPTOM OCCUR?	**THE SYMPTOM DID OCCUR AND WAS ……TROUBLESOME TO ME**				
		Not at all	A little	Moderately	Very	Extremely
23. Frequent need to urinate?	No Yes→→→→	1	2	3	4	5
24. Pains in the chest or heart region?	No Yes→→→→	1	2	3	4	5
25. Burning pain in the legs during the day?	No Yes→→→→	1	2	3	4	5
26. Tingling or prickling sensations in hands or fingers?	No Yes→→→→	1	2	3	4	5
27. Easily irritated or annoyed?	No Yes→→→→	1	2	3	4	5
28. Sudden deterioration of vision?	No Yes→→→→	1	2	3	4	5
29. Odd feeling in (lower) legs or feet when touched?	No Yes→→→→	1	2	3	4	5
30. Shortness of breath during physical exertion (walking, chores)?	No Yes→→→→	1	2	3	4	5
31. Fuzzy feeling in your head (difficulty thinking clearly)?	No Yes→→→→	1	2	3	4	5
32. Drinking a lot (all sorts of beverages)?	No Yes→→→→	1	2	3	4	5
33. Difficulty paying attention?	No Yes→→→→	1	2	3	4	5
34. Tingling or prickling sensations in lower legs or feet?	No Yes→→→→	1	2	3	4	5
Any other symptoms: 35.	Yes→→→→	1	2	3	4	5
36.	Yes→→→→	1	2	3	4	5
37.	Yes→→→→	1	2	3	4	5

SF-12 v2 ™ Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
O	O	O	O	O

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O	O	O
b. Climbing several flights of stairs	O	O	O

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	O	O	O	O	O
b. Were limited in the kind of work or other activities	O	O	O	O	O

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. <u>Accomplished less</u> than you would like	O	O	O	O	O
b. Did work or activities <u>less carefully than usual</u>	O	O	O	O	O

5. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
O	O	O	O	O

6. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the <u>past 4 weeks</u> . . .

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	O	O	O	O	O
b. Did you have a lot of energy?	O	O	O	O	O
c. Have you felt downhearted and depressed?	O	O	O	O	O

7. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
O	O	O	O	O

Thank you for completing these questions!

Well-Being Questionnaire (W-BQ12)

Please circle one number on each scale, from 3 (all the time) to 0 (not at all), to indicate how often you feel each statement has applied to you in the past few weeks.

	all the time			not at all
1. I have crying spells or feel like it ……	3	2	1	0
2. I feel downhearted and blue ……	3	2	1	0
3. I feel afraid for no reason at all ……	3	2	1	0
4. I get upset easily or feel panicky ……	3	2	1	0
5. I feel energetic, active, or vigorous ……	3	2	1	0
6. I feel dull or sluggish ……	3	2	1	0
7. I feel tired, worn out, or exhausted ……	3	2	1	0
8. I have been waking up feeling fresh and rested ……	3	2	1	0
9. I have been happy, satisfied, or pleased with my personal life ……	3	2	1	0
10. I have lived the kind of life I wanted to ……	3	2	1	0
11. I have felt eager to tackle my daily tasks or make new decisions ……	3	2	1	0
12. I have felt I could easily handle or cope with any serious problem or major change in my life……	3	2	1	0

Please make sure that you have considered each of the 12 statements and have circled one number in response to each statement.

Appraisal of Diabetes Scale

People differ in their thoughts and feelings about having diabetes. We would like to know how you feel about having diabetes. Therefore, please circle the answer to each question which is closest to the way *you* feel. Please give your honest feelings—*we are interested in how you feel*, not what your doctor or family may think.

1. How upsetting is having diabetes for you?

1	2	3	4	5
Not at all	Slightly upsetting	Moderately upsetting	Very upsetting	Extremely upsetting

2. How much control over your diabetes do you have?

1	2	3	4	5
None at all	Slight amount	Moderate amount	Large amount	Total amount

3. How much uncertainty do you currently experience in your life as a result of being diabetic?

1	2	3	4	5
None at all	Slight amount	Moderate amount	Large amount	Extremely large amount

4. How likely is your diabetes to worsen over the next several years? (Try to give an estimate based on your personal feeling rather than based on a rational judgment.)

1	2	3	4	5
Not likely at all	Slightly likely	Moderately likely	Very likely	Extremely likely

5. Do you believe that achieving good diabetic control is due to your efforts as compared to factors which are beyond your control?

1	2	3	4	5
Totally because of me	Mostly because of me	Partly because of me and partly because of other factors	Mostly because of other factors	Totally because of other factors

6. How effective are you in coping with your diabetes?

1	2	3	4	5
Not at all	Slightly effective	Moderately effective	Very effective	Extremely effective

7. To what degree does your diabetes get in the way of your developing life goals?

1	2	3	4	5
Not at all	Slight amount	Moderate amount	Large amount	Extremely large amount

Ferrans and Powers

QUALITY OF LIFE INDEX©
DIABETES VERSION – III

PART 1. For each of the following, please choose the answer that best describes how ***satisfied*** you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

HOW *SATISFIED* ARE YOU WITH:	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of energy you have for everyday activities?	1	2	3	4	5	6
4. Your ability to take care of yourself without help?	1	2	3	4	5	6
5. Your ability to control your blood sugar?	1	2	3	4	5	6
6. The changes you have had to make in your life because of diabetes (such as diet, exercise, taking insulin or diabetes pill, checking blood sugar)?	1	2	3	4	5	6
7. The amount of control you have over your life?	1	2	3	4	5	6
8. Your chances of living as long as you would like?	1	2	3	4	5	6
9. Your family's health?	1	2	3	4	5	6
10. Your children?	1	2	3	4	5	6
11. Your family's happiness?	1	2	3	4	5	6
12. Your sex life?	1	2	3	4	5	6
13. Your spouse, lover, or partner?	1	2	3	4	5	6
14. Your friends?	1	2	3	4	5	6
15. The emotional support you get from your family?	1	2	3	4	5	6

(Please Go To Next Page)

HOW *SATISFIED* ARE YOU WITH:	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
16. The emotional support that you get from people other than your family?	1	2	3	4	5	6
17. Your ability to take care of family responsibilities?	1	2	3	4	5	6
18. How useful you are to others?	1	2	3	4	5	6
19. The amount of worries in your life?	1	2	3	4	5	6
20. Your neighborhood?	1	2	3	4	5	6
21. Your home, apartment, or place where you live?	1	2	3	4	5	6
22. Your job (if employed)?	1	2	3	4	5	6
23. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
24. Your education?	1	2	3	4	5	6
25. How well you take care of your financial needs?	1	2	3	4	5	6
26. The things that you do for fun?	1	2	3	4	5	6
27. Your chances for a happy future?	1	2	3	4	5	6
28. Your peace of mind?	1	2	3	4	5	6
29. Your faith in God?	1	2	3	4	5	6
30. Your achievement of personal goals?	1	2	3	4	5	6
31. Your happiness in general?	1	2	3	4	5	6
32. Your life in general?	1	2	3	4	5	6
33. Your personal appearance?	1	2	3	4	5	6
34. Yourself in general?	1	2	3	4	5	6

(Please Go To Next Page)

PART 2. For each of the following, please choose the answer that best describes how ***important*** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

HOW *IMPORTANT* TO YOU IS:	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. Having enough energy for everyday activities?	1	2	3	4	5	6
4. Taking care of yourself without help?	1	2	3	4	5	6
5. Controlling your blood sugar?	1	2	3	4	5	6
6. The changes you have had to make in your life because of diabetes (such as diet, exercise, taking insulin or diabetes pill, checking blood sugar)?	1	2	3	4	5	6
7. Having control over your life?	1	2	3	4	5	6
8. Living as long as you would like?	1	2	3	4	5	6
9. Your family's health?	1	2	3	4	5	6
10. Your children?	1	2	3	4	5	6
11. Your family's happiness?	1	2	3	4	5	6
12. Your sex life?	1	2	3	4	5	6
13. Your spouse, lover, or partner?	1	2	3	4	5	6
14. Your friends?	1	2	3	4	5	6
15. The emotional support you get from your family?	1	2	3	4	5	6
16. The emotional support you get from people other than your family?	1	2	3	4	5	6

(Please Go To Next Page)

HOW *IMPORTANT* TO YOU IS:	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
17. Taking care of family responsibilities?	1	2	3	4	5	6
18. Being useful to others?	1	2	3	4	5	6
19. Having no worries?	1	2	3	4	5	6
20. Your neighborhood?	1	2	3	4	5	6
21. Your home, apartment, or place where you live?	1	2	3	4	5	6
22. Your job (if employed)?	1	2	3	4	5	6
23. Having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
24. Your education?	1	2	3	4	5	6
25. Being able to take care of your financial needs?	1	2	3	4	5	6
26. Doing things for fun?	1	2	3	4	5	6
27. Having a happy future?	1	2	3	4	5	6
28. Peace of mind?	1	2	3	4	5	6
29. Your faith in God?	1	2	3	4	5	6
30. Achieving your personal goals?	1	2	3	4	5	6
31. Your happiness in general?	1	2	3	4	5	6
32. Being satisfied with life?	1	2	3	4	5	6
33. Your personal appearance?	1	2	3	4	5	6
34. Are you to yourself?	1	2	3	4	5	6

APPENDIX G

MISSING DATA

Missing Data Replaced by Imputation

Measurement Tool	Item	Missing		Group Mean	Individual Mean	Replaced Value
		Count (n)	%			
Health Questionnaire	Duration of Diabetes	4	3.7	12.6	--	12.5
Access to diabetes care item	CIRS #15	1	0.9	4.11	3.5	4
CIRS	#5	1	0.9	2.39	1.5	2
	#11	1	0.9	1.51	2.3	2
	#14	1	0.9	3.01	2.0	2
	#17	1	0.9	1.90	2.0	2
Well-Being Questionnaire 12	#4	1	0.9	0.53	0.66	1
DSC-R	#16	1	0.9	1.47	2.0	2
	#29	1	0.9	0.54	2.0	1
SF-12 Health Survey (v2)	#2a	1	0.9	2.28	1.6	2
Appraisal of Diabetes Scale	#2	1	0.9	3.64	2.7	3

Missing Data Not Replaced

Measurement Tool	Item Description	Missing		Reason not replaced
		Count (n)	%	
Demographics Questionnaire	Income	8	7.5	[2]
	Height	1	0.9	[2]
	Weight	1	0.9	[2]
CIRS	#20 (work-related)	68	63.6	Expected missing[3]
	#21 (work-related)	72	67.3	
	#22 (work related)	72	67.3	
Health History Questionnaire	Detached Retina	1	0.9	Subject (#109) did not know history
	Retinopathy	1	0.9	
	Laser Eye Surgery	1	0.9	
Glycemic control	A1C	6	5.6	[2]
Well-Being Questionnaire 12	#5 (energy/vigor)	1	0.9	Subj. (#135) left blank 2/4 items on subscale
	#6 (sluggish)	1	0.9	
Appraisal of Diabetes Scale	#3 (uncertainty)	1	0.9	Subject (#178) left blank 3/7 of instrument
	#5 (locus of control)	1	0.9	
	#7 (life goals impact)	1	0.9	
Quality of Life Index	SAT9 (family health)	1	0.9	Subject (#194) left blank all family subscale items
	IMP9 (family health)	1	0.9	
	SAT11 (family happiness)	1	0.9	
	IMP11(family happiness)	1	0.9	
	SAT15 (family support)	1	0.9	
	IMP15 (family support)	1	0.9	
	SAT10 (children)	10	9.3	Expected missing[4]
	IMP10 (children)	10	9.3	
	SAT12 (sex life)	15	14	
	IMP12 (sex life)	18	16.8	
	SAT13 (spouse/partner)	21	19.6	
	IMP13 (spouse/partner)	20	18.7	
	SAT22 (work-related)	72	67.3	Expected missing[3]
	IMP22 (work-related)	69	64.5	
	SAT23 (work-related)	45	42.1	
	IMP23 (work-related)	37	34.6	

[2]Data cannot be deductively imputed without excessive risk of distorting relationships between variables.
[3]Missing data related to employment was expected as 67.3 % subjects not currently working outside the home.
[4] Missing data related to partner/children was expected as 42% of subjects are unpartnered (single, divorced, separated or widowed) and 9.3% of subjects stated no children.

APPENDIX H

DATA ANALYSES ASSUMPTIONS

Assumptions for ANOVA

Assumption	Description	Assumption Met
Homogeneity of Variance (Homoscedasticity)	Similar variance in each experimental condition/group	Levene's Test non-significant
Independent Observations	-Uncorrelated error terms -Uncorrelated independent variables	Durbin-Watson = 1 to 3
Dependent variable is an interval or continuous scale	Variable is interval or greater scale	Yes
Normality (of residuals)	Distributions *within groups* are normally distributed	Yes

Tests of Normal Distribution

Test	Description	Quality of Life (QLI)	Assumption met?
Skewness	Symmetry (should be zero)	-0.623	No
Kurtosis	Distortion from bell-curve (should be zero)	-0.002	Yes
Kolmogorov-Simirnov	Goodness-of-fit test; should be >.05	0.200	Yes
Shapiro-Wilk	Comparison to normal distribution, should be >.05	0.007	No

Assumptions for MANOVA

Assumption	Description	Assumption Met
Independence	Uncorrelated independent variables	Wilks' Lambda significant
Random Sampling	Dependent variable is randomly sampled from population at interval scale (at least)	Yes
Multivariate Normality	Dependent variables are normally distributed *within groups*	Yes
Homogeneity of Covariance Matrices	Variance-covariance matrices of groups are equal	Levene's test then Box's Test (both nonsignificant)

Assumptions for Multiple Regression

Assumption	Description	Assumption Met
Variable Type	-Interval or greater scale -Unbounded = no constraints per instrument's scale	Yes
Variance is non-zero	Predictors' variance ≠ zero	Yes, per descriptive statistics
Multicollinearity	Predictors are not highly correlated	VIF should be <10 Tolerance > 0.1
Predictors not correlated with external variables	External variables are those not included in the analysis but are related to the outcome	Review of literature per Chapter 2.
Homoscedasticity	Predictor residuals should have similar variance	Non-significant Levene's test
Independent error terms	Subjects' residuals are not correlated	Durbin-Watson = 1 to 3
Normally distributed errors	Residuals are random, normally distributed, mean = zero.	Yes
Independence	All dependent variable measurements come from separate subjects	Chapter 3, methods show simultaneous cross-sectional data collection
Linearity	Model relationship is linear	Yes

Note: Assumptions and descriptions are from Field, 2009.

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VITA

Sandra McCormick graduated with her Bachelor of Arts in Psychology from the University of Notre Dame in 1997. She graduated with her Bachelor of Science in Nursing from St. Louis University in 1998. Ms. McCormick began her nursing career at Loyola University Medical Center on an inpatient medical-surgery-transplant unit. In 2000, Ms. McCormick began working in the Emergency Department of Loyola University Medical Center, where she remained through 2013. During her employment at Loyola University Medical Center, Ms. McCormick enjoyed precepting new staff nurses. She also precepted interdisciplinary health students, including nursing, medical, and paramedic students. Moreover, she was an assistant instructor in the nursing skills laboratory at Loyola University Chicago, where she further discovered her love of teaching.

Sandra McCormick began the BSN to PhD program at Loyola University Chicago in 2003. She worked as a teaching assistant in Loyola's undergraduate nursing clinicals. Sandra McCormick has presented her research at the Midwest Nursing Research Society and the Ruth K. Palmer Symposium at Loyola University Chicago. Ms. McCormick has served as mentor to many undergraduate and graduate nursing students. In addition, she has given guest lectures to Loyola's Undergraduate nursing students. Ms. McCormick looks forward to sharing her love of nursing as a faculty member.